cartridge to mix with the lyophilized drug. The syringe is then removed and discarded.

A transfer needle 32, such as those manufactured by Becton-Dickinson, can then be threadedly attached to cap 20 where connector 30 was attached during reconstitution. This is shown in Fig. 6. The typical transfer needle 32 is a double-ended needle 110, which extends in one direction through hole 46 in top 41 and seal 52 to communicate with the reconstituted drug within the cartridge. Needle 110 is secured in a needle housing 112 and protected during nonuse by a plastic cap 114 and needle assembly protector cap 116.

Referring in particular now to Fig. 8, cartridge assembly 90 is threadedly attached to an injector pen 104, such as that manufactured by Disetronic AB of Burgdorf, Switzerland. A plunger rod 108 fits into recess 107 of rod tip 71 in order to effect ejection of the reconstituted drug from the cartridge. The inside length of rod tip 71 is adapted to retain the injector pen plunger rod 108 during the injector pen's compression and retraction stroke. When the drug is to be administered to the patient, the needle assembly 32 as shown in Fig. 6 is attached to cap 20 as described hereinabove.

One such type of injector pen is shown in Fig. 11 and its operation described in conjunction with additional Figs. 12-14. Referring to Fig. 11, cartridge assembly 90 is shown connected to injector pen 104 via complementary threads 86, 101. Injector pen 104 includes a pen rod 108, a dose knob 118 and a release button 120. Pen rod 108 fits into a suitable mechanism within pen body 106 for providing the injector function as described below in conjunction with Figs. 12-14.

It should be noted with respect to Figs. 12-14 that for simplicity of discussion and understanding of an aspect of the present invention that only rubber plunger 54 and plunger rod tip 71 of the cartridge assembly are shown in relationship to pen 104 and, in particular pen

rod 108. To load the assembly for the first time, release button 120 is pushed such that dose knob 118 pops out. At this point, pen rod 108 retracts a known, or predetermined distance, for example 8.1 millimeters away from plunger 54 within recess 107. Dose knob 118 is then turned until dose knob 118 stops which causes pen rod 108 to travel forward towards plunger 54 a set maximum amount for purging. Upon retraction, pen rod 108 cooperates with rod tip 71 in that pen rod 108 does not travel any more than 8.1 millimeters out of the 8.9 mm (for example) recess 107 of the rod tip 71. End 109 of plunger rod 108 thus never retracts past a plane defined at the end 83 of rod tip 71 perpendicular to an axis of elongation of rod tip 71. Thus, rod 108 never disengages from recess 107.

The rod tip, being an integral part of the housing for the cartridge assembly prevents the plunger 54 in the cartridge from being forced out during the reconstitution process. Further, rod tip 71 allows movement required by the pen's plunger rod 108 during dose setting and injection. When dose knob 118 is pushed in, the unit purges 95 percent of all of the air in the cartridge in order to obtain a proper head space. Thus, after reconstitution, and initial purging, the injector pen assembly is ready for the administration process as shown in Fig. 11.

In order to administer the drug to the patient, release button 120 is pressed which causes dose knob 118 to pop out and correspondingly cause pen rod 108 to retract the 8.1 mm maximum travel distance within the 8.9 mm rod tip 71, each action being depicted by respective arrows in Fig. 12. As noted hereinabove, end 109 never retracts past end 83. Dose knob 118 is then turned through so many clicks, the clicks corresponding to volume units of dosage depending on the required amount of dosage. Each click corresponding to a given volume of injectionable liquid. This is depicted in Fig. 13. As the required number of clicks are set via dose knob 118,

pen rod 108 correspondingly moves forward an amount equal to the number of clicks, with each click correspondingly moving pen rod 108 a predetermined distance being coordinated with a set dosage amount.

As shown in Fig. 14, when dose knob 118 is depressed, pen rod 108 thus contacts rod head 73 of rod tip 71 to administer the drug by traveling the 8.1 mm distance. Upon retraction of pen rod 108 in order to administer another dose, pen rod 108 retracts the set 8.1 mm distance within the 8.9 mm recess 107. This ensures that pen rod 108 never comes out of rod tip 107.

The process as depicted in Figs. 12-14 is repeated at the prescribed times until all of the drug has been administered. A dose indication device 122 is provided to visually indicate the dosage set by dose knob 118. Such dose indication may be purely mechanical in nature or electronic, such as an LCD display.

Once the entire drug has been administered to the patient, the entire cartridge assembly and patient needle assembly is then discarded. The injector pen is then ready for another cartridge assembly 90.

While this invention has been described as having a preferred design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

CLAIMS

1. A method of lyophilizing and sealing an injectionable product within a cartridge, the method comprising the steps of: providing an elongate cartridge (58) having on a first end thereof a shoulder (66), a rim (63) defining a first opening and having a circumferential radially outwardly extending flange (62) adjacent said first opening, and a neck (64) disposed axially between said flange and shoulder, said neck having a diameter smaller than said flange and shoulder, said cartridge including a second opening on a second end thereof distal said first opening; and inserting a plunger (54) in said second opening; characterized by:

providing a cap (20) having a cylindrical portion and a seal (52), said cylindrical portion including an open bottom receivable over said neck, said cap including a top having an opening therein for receipt of a needle therethrough, at least one vent (34) circumferentially disposed in said cap, and at least two deformable ledges (38,40) on said cap extending radially inwardly from said cylindrical portion axially below said vent, said seal being axially disposed between said vent and said top so as to block said top opening;

inserting the product to be lyophilized into said cartridge (58);

placing said cap onto said cartridge such that said deformable ledges (38,40) rest upon said flange (62) and said vent is in fluid communication with said cartridge first opening; placing said cartridge with said cap in a lyophilizing chamber; lyophilizing the product; and

closing said cap by exerting a downward pressure upon said cap such that said deformable ledges yieldably snap around said flange (62) and into said neck to be lockingly retained therein, said vent (34) is blocked from communication with said cartridge first opening, and said seal (52) is pressed into sealing engagement with said rim (63) by downward pressure exerted by said top thereby

providing an air impermeable barrier between said top opening and said cartridge first opening.

2. The method of claim 1, characterized in that the step of closing said cap (20) is preceded by the steps of purging oxygen from said cartridge (58) and providing a nitrogen overlay in said cartridge.

3. The method of claim 1, further characterized by: providing a sleeve (78) having a first open end for receiving said cartridge (58) and a radially inwardly extending stop (84); and placing said cartridge into said first open end of said sleeve such that said cartridge is positively axially retained in said sleeve against said stop.

4. The method of claim 3, characterized by the subsequent step of permanently attaching said sleeve (78) to said cap (20).

5. The method of claim 3, characterized in that said sleeve (78) includes a second open end distal said first open end and axially below said sleeve stop, and the step of placing said cartridge into said sleeve is preceded by the step of inserting a plunger rod tip (71) having a head (73) in said sleeve such that said plunger rod tip extends from said second opening and said head is axially adjacent said plunger (54).

6. The method of claim 5, further characterized by the step of capturing said head (73) between said sleeve ledge (84) and said plunger (54).

7. The method of claim 1, characterized in that the step of placing the cartridge (58) in a lyophilizing chamber includes supporting said cartridge on a first surface (74), and the step of closing said cap includes exerting a downward pressure upon said cap (20) by contact of a second surface (72) upon said cap induced by relative vertical movement between said first and second surfaces.

8. A cartridge assembly for holding a lyophilized drug and forming a disposable part of an injection pen, the cartridge assembly comprising:

an elongate cartridge (58) having on a first end thereof a shoulder (66), and a rim (63) defining a first opening and having a circumferential radially outwardly extending flange (62) adjacent said first opening and a neck (64) disposed axially between said flange and shoulder, said neck having a diameter smaller than said flange and shoulder, said cartridge including a second opening on a second end thereof distal said first opening;

a cap (20) disposed on said first end of said cartridge, said cap having a first cylindrical portion including an open bottom received over said first end, a top having an opening therein for receipt of a needle therethrough, and at least two elastically deformable ledges (38,40) extending radially inwardly from said first cylindrical portion and lockingly retained under said neck flange;

a resilient seal (52) in said cap disposed between said first opening and said top opening and forming an impermeable barrier therebetween a vent opening in said cap below said seal; a sleeve (78) radially disposed about and permanently attached to said cap; and

a plunger rod tip (71) slidably disposed in said sleeve, said plunger rod tip including a head (73) axially adjacent said plunger for exerting pressure against said plunger during administration of the drug.

9. The cartridge assembly of claim 8, characterized in that said sleeve (78) includes a first cylindrical portion adapted to receive said cartridge and a second cylindrical portion axially below said first cylindrical portion and concentric therewith, and a radially inward circumferentially extending ledge (84) defined at the junction of said first and second cylinder for axially retaining said one end of said cartridge.

10. The cartridge assembly of claim 8, characterized in that said rim (63) of said cartridge outwardly tapers for compressingly sealing said resilient seal (52) between said cartridge and said cap.

11. The cartridge assembly of claim 8, characterized in that said cap (20) includes an oval shaped wall carrying said ledges (38,40) wherein said wall is thinner along the major axis of the oval than along the minor axis of the oval, and said ledges are disposed generally on the minor axis of the oval.

12. The cap and cartridge assembly of claim 8, characterized in that said deformable ledge comprises two circumferential and inwardly extending ledges (38,40) separated by two arcuate portions of an oval-shaped wall (50) and said ledges are located on the minor axis of said oval-shaped wall.

13. The cap and cartridge assembly of claim 12, characterized in that said oval-shaped wall (50) is thinner along the major axis of the oval than along the minor axis of the oval.

14. A method reconstituting a lyophilized compound, the lyophilized compound contained within an interior space defined by an inner wall of a cartridge (59) having an inlet at one end thereof, the method comprising the steps of: attaching a connector (30) to the inlet end of the cartridge, the connector having an interior space and defining an axis along a longitudinal length thereof, the axis of the connector forming an oblique angle relative to the axis of the cartridge; placing a syringe (96) having a needle (98) and containing the diluent into the interior space of the connector, such that the needle (98) is oriented obliquely toward the inner wall of the cartridge; and injecting a diluent from the syringe into the cartridge via the inlet such that the diluent impinges on and runs down the inner wall of the cartridge before contacting the compound (70) whereby foaming of the compound is prevented.

15. An apparatus for reconstituting a lyophilized drug contained within an inner space of a cartridge, the cartridge (59) having an inlet on one end thereof, and defining a longitudinal axis extending through the inlet,

the apparatus comprising: a connector (30) releasably secured to the inlet end of the cartridge and adapted to receive and hold a syringe (96) containing a diluent, the connector having a first portion (111) defining a longitudinal axis which forms an oblique angle with the longitudinal axis of the cartridge, the syringe being supported by the connector at the oblique angle whereby the diluent is injected into the cartridge via the inlet at the oblique angle.

16. The apparatus of claim 15, characterized in that said connector (30) is received on the inlet end of the cartridge, the connector further including a second portion (113) eccentric with said first portion, said second portion having a larger diameter than a diameter of said first portion and adapted to retain and support the syringe.

17. An injector pen and cartridge apparatus for administering a drug, the apparatus comprising: a cartridge assembly (90) having a cartridge with a movable plunger (54) therein and an inlet on one end thereof, said cartridge assembly including a rod tip (71) disposed axially adjacent said plunger and adapted to exert pressure upon said plunger for dispensing the drug from said cartridge, said rod tip including a recess (107) of a given axial length therein; and an injector pen releasably engaged with said cartridge assembly, said pen including a movable rod (108) received in said recess (107) and engaging said rod tip in order to advance said rod tip during dispensing of the drug; characterized in that said movable rod (108) has a retraction travel length that is less than the axial length of said recess whereby said movable rod remains engaged with said rod tip.

18. The cartridge assembly of Claim 17 characterized in that said plunger rod tip (73) is captured by said ledge (84) of said sleeve to thereby retain said plunger rod tip in said sleeve.

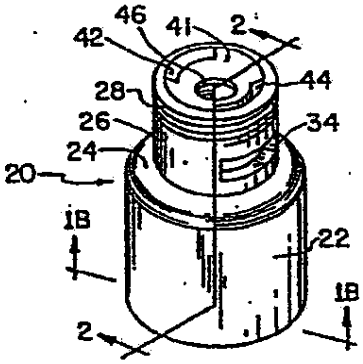


FIG. 1A

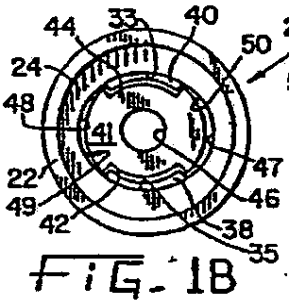


FIG. 1B

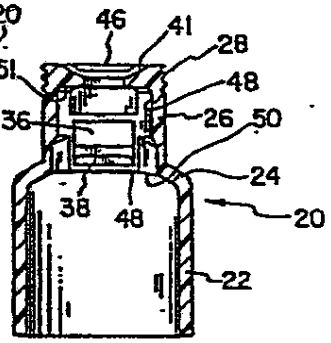


FIG. 2

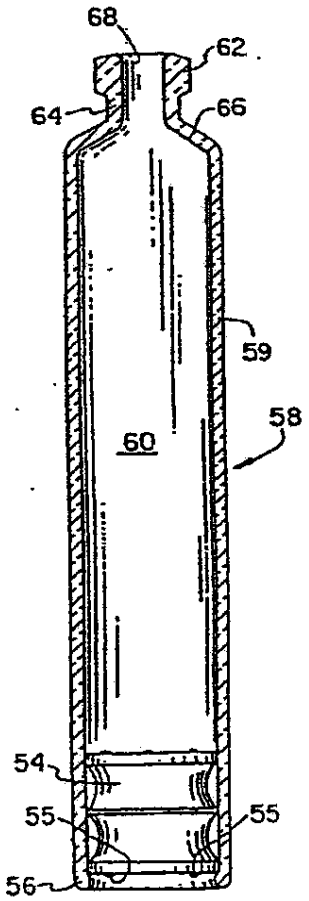


FIG. 3

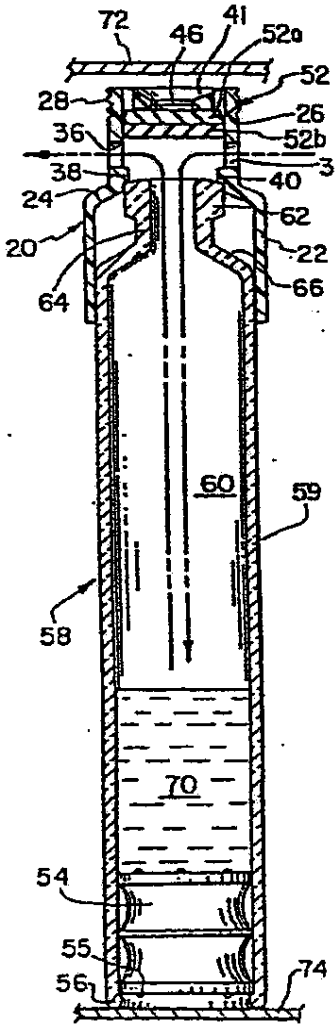


FIG. 4

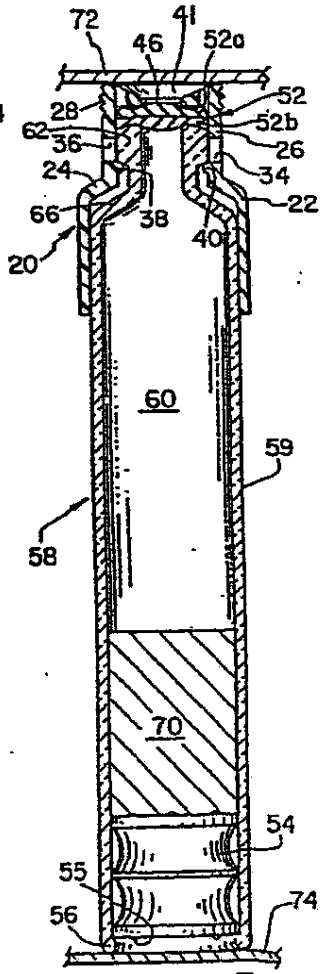
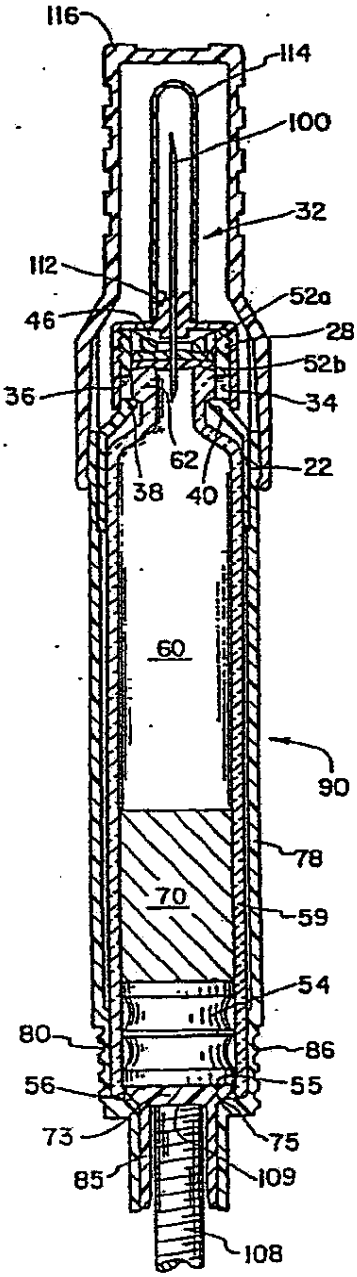


FIG. 5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32
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52b
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FIG. 6

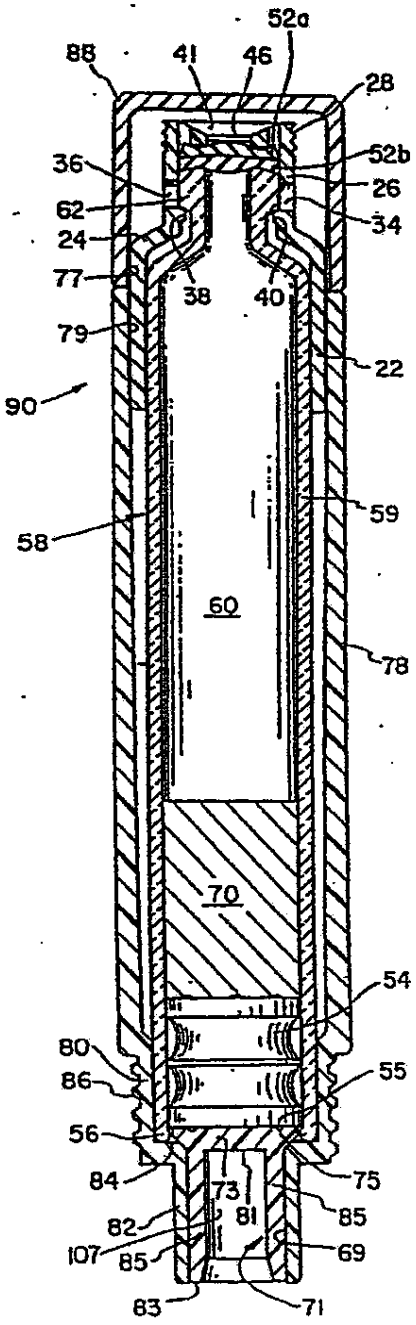
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FIG. 7

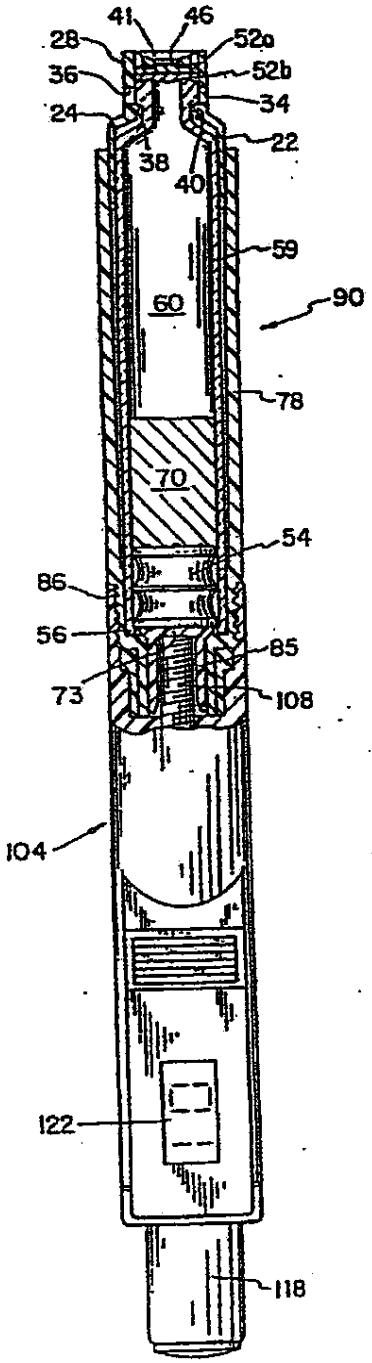
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FIG. 8

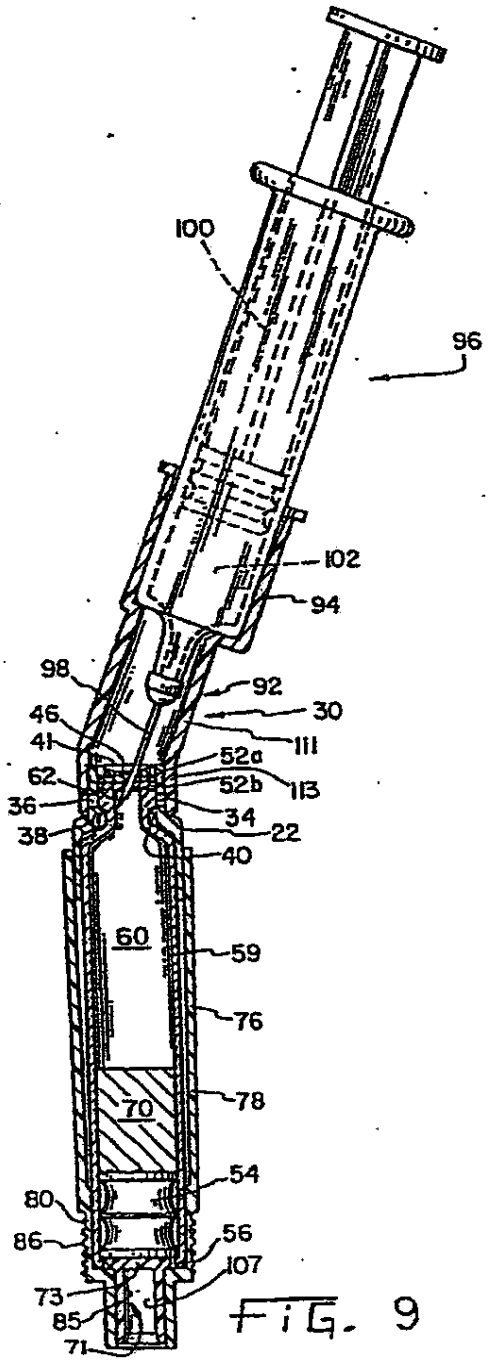
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FIG. 9

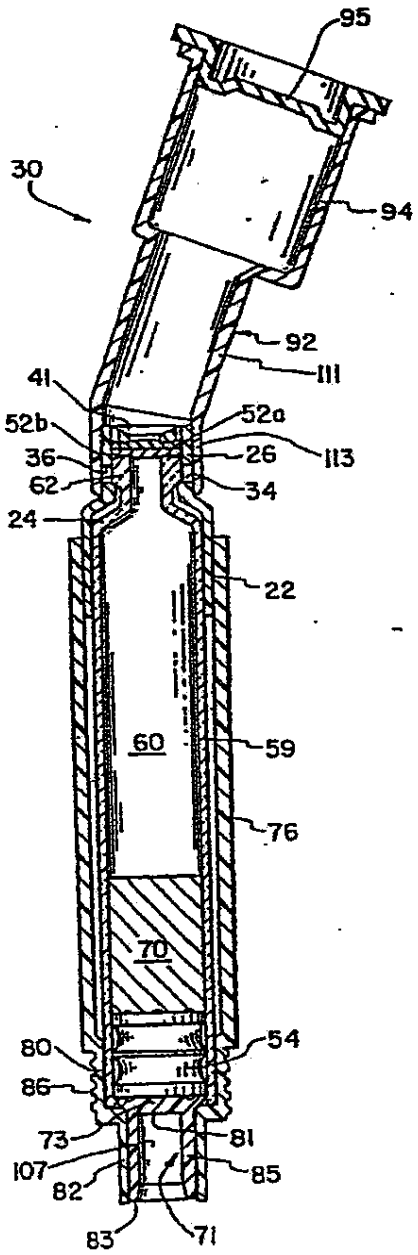
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FIG. 10

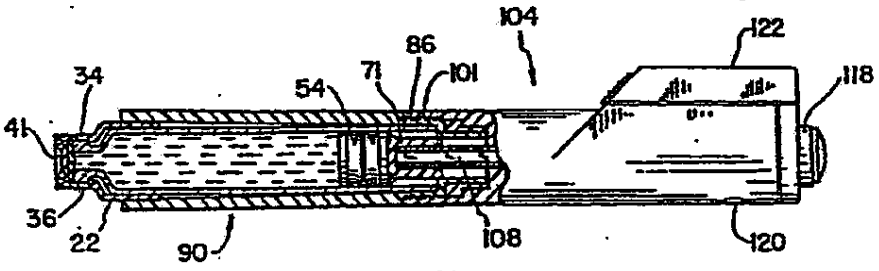

FIG. 11

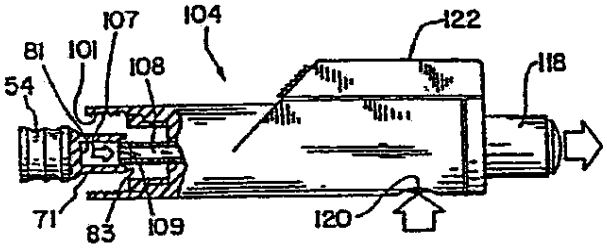

FIG. 12

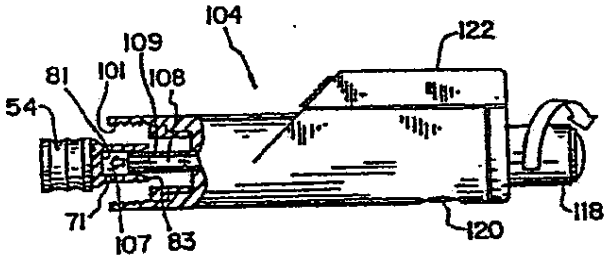

FIG. 13

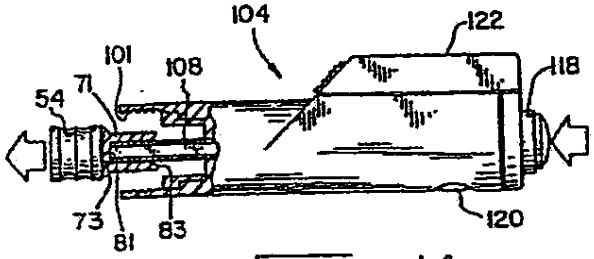

FIG. 14

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Published
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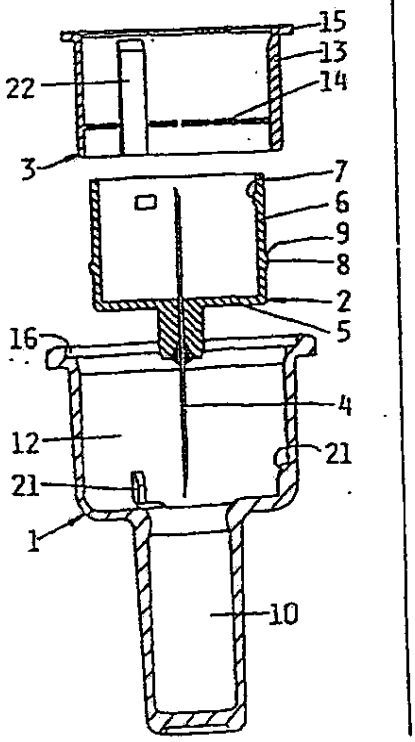
(54) Title: NEEDLE MAGAZINE

(57) Abstract

A magazine for storing and final disposal of a snap-on needle unit (2) has a compartment (1) having a bottom, a cylindric side wall, and an access opening, which compartment accomodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment. A circle of tongue shaped protrusions (14) are at one end thereof hinged at the inner surface of the side wall of the compartment and are at their other end free. The length of the protrusions exceeds the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.



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VN	Viet Nam

NEEDLE MAGAZINE

The invention relates to a magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a cylindric outer wall.

A snap-on needle unit is a unit which may be mounted on a syringe by an axial movement of the syringe and the needle unit towards each other. During this movement a needle receiving part of the syringe is passed into a sleeve of a needle hub forming part of the needle unit until protrusions on the inner surface of the sleeve engage recesses in the needle receiving part.

In opposition to needle units which a screwed onto the syringe an axial pressure must be exerted on the needle unit and the syringe to provide the snap engagement between the two parts. Correspondingly a certain axial force must be used to pull the syringe and the needle unit apart again when after use the needle is removed from the syringe for final disposal.

During mounting and dismounting of the needle unit it is important that the outer pointed end of the needle is protected so that neither the user nor an assisting person scratch himself by this pointed end. Therefore the needle unit is stored in a magazine which covers the needle unit only leaving free the opening wherein the needle receiving part of the syringe shall be inserted.

It is the object of the invention to provide a magazine which may further be used for removing a used needle from the syringe and for keeping it locked in the magazine in a position so that the used needle may not be removed from the magazine after the reinsertion therein. Further it is the object of the invention to show appropriate modifications of the needle unit design which ensures a good collaboration between the needle unit and the magazine.

A magazine according to the invention is characterized in that it has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall

of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped flexible protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

When the needle unit is stored in the magazine the bottom of this magazine supports the needle hub when a needle receiving end of a syringe is pressed into the needle hub to mount this hub onto the syringe. When the needle hub is snap engaged to the syringe it may easily be drawn out of the magazine with the protrusions sliding along the cylindric outer surface of the needle hub. When a used needle unit is reinserted into the magazine the flexible protrusions will have assumed a position wherein the opening defined by the free end of the protrusion has a smaller diameter than has the cylindric part of the needle hub. When the hub is inserted the protrusions will be deflected with their free ends pointing toward the bottom of the compartment until these protrusions assume an oblique position where the cylindric part of the needle unit may pass the free ends of the protrusions which may now slide over the surface of the cylindric part during the further insertion of the needle unit into the magazine. When hereafter the syringe is retracted the protrusions will jam in the gap and retain the needle unit back in the magazine so that pulling the syringe and the magazine away from each other will result in a release of the snap engagement between the needle unit and the syringe.

Not to rely only on the jamming of the protrusions in the gap between the compartment wall and the needle unit the free end of the protrusion abutting the cylindric part of the needle unit may be sharpened so that they will cut into this cylindric part when an attempt is made to move this unit in a direction opposite the direction indicated by the protrusions.

The circle of sharp ended flexible protrusions may appropriately be provided as radially inward extending tongues in a metal ring fixed to the inner wall of the compartment of the magazine.

Due to the locking function of the protrusions the new needle units which are sold stored in the magazine may not just be inserted into the magazine as this would put the protrusion in their locking position. Therefore a special packing technique must be used to ensure that the protrusions of magazines with new needle units ready for use are pointing towards the access opening of the magazine. This may be obtained when the protrusions are provided on the inner surface of sleeve which as a lining is inserted and secured in the compartment. This construction allows that a new and unused needle unit is placed in the magazine whereafter the lining sleeve is inserted in the compartment through the access opening thereof. During the insertion of the lining the free ends of the protrusions will be deflected towards the access opening by the cylindric part of the needle unit already placed in the magazine. With this direction of the protrusions the needle unit may easily be drawn out of the magazine.

The collabpration of the locking means of the magazine and the cylindric part of the needle unit may be enhanced by appropriate design of said cylindric part. This design may consist in the provision of at least one circumferential edge on the cylindric wall of the needle unit. The edge may be drawn past the protrusions as long as these protrusions point away from the edge, but a jamming will occur when the ends of the protrusions abuts against the edge as the protrusion not only have to be deflected but must be crumbled to let the edge pass.

Such an edge may be provided by the ends of a number of circumferentially spaced axial ribs on the cylindric outer wall of the needle unit.

In another embodiment the cylindric part of the needle unit may be provided with a circumferential ring shaped protrusion to provide the circumferential edge.

In still another embodiment the circumferential edge may be provided as the edge of a circumferential recess in the cylindric part of the needle hub.

In the following the invention is further described with reference to the drawings, wherein

Figure 1 shows a sectional view of a not assembled embodiment of a magazine and needle according to the invention,

Figure 2 shows a sectional view of the embodiment in figure 1 assembled for storage,

Figure 3 shows a sectional view of the embodiment in figure 2 with the needle finally disposed of in the magazine,

Figure 4 shows a sectional view of another embodiment of a magazine with a stored needle unit,

Figure 5 shows a locking ring for the magazine shown in figure 4, and

Figure 6 shows an exploded view of an embodiment of a magazine with a needle before assembling.

In figure 1 is shown a magazine 1, a needle unit 2, and a locking sleeve 3 in a position ready to be assembled to store the needle unit in the magazine in a way making it possible to take the needle unit from the magazine and to reinsert the needle unit in the magazine for final disposal.

The needle unit 2 comprises an injection needle 4 carried in a needle hub comprising a bottom 5 which carries a cylindric sleeve 6 surrounding one end of the needle 4 and having at its inner surface protrusions 7 for engagement with recesses in a needle receiving part of a syringe. On its outer surface the sleeve 6 has a circumferential rib 8 exhibiting an edge 9 facing the open syringe receiving end of the sleeve.

The magazine 1 comprises a needle accommodating compartment 10, needle hub support ribs 21, and a sleeve accommodating compartment 12. The needle unit 2 is inserted in the magazine 1 with the end of the needle not surrounded by the sleeve 6 inserted in the compartment 10 and the bottom 5 of the needle hub abutting against the needle support ribs 21. Thereby the sleeve 6 will be centered in the compartment 12 leaving a uniform gap between the outer surface of the sleeve 6 and the inner surface of the cylindric wall of the compartment 12 allowing the locking sleeve 3 to be pressed in through an open end of the compartment 12.

The locking sleeve 3 has a cylindric wall 13 which is at its inner surface along a circle in a plane perpendicular to the axis of the sleeve 13 provided with tongue shaped projections 14 which are flexible in their connection to the inner wall of the locking sleeve 13 and which extend radially so that the circle defined by their free ends has a minor diameter than has the needle hub. Consequently, when the locking sleeve 3 is inserted in the gap between the needle hub and the inner wall of the compartment 12 the needle hub will abut the projections 14 and deflect them to adopt an oblique position with their free ends pointing towards the open end of the magazine as shown in figure 2. The locking sleeve 3 is secured in the compartment 12, e.g. by having a flange 15 which is received in a recess 16 surrounding the access opening of the magazine and a gluing or welding being established between the flange 15 and the recess 16. Alternatively an irreversible snap lock connection may be provided between the outer surface of the locking sleeve and the inner cylindric surface of the compartment 12.

When the needle unit 2 is positioned in the magazine 1 and the locking sleeve is inserted in the gap between the needle hub and the magazine the magazine is closed by a membrane 17 covering the access opening of the magazine and the needle unit may in this way be maintained sterile as long as it is stored in the magazine. The membrane may be made from paper which does not allow germs to pass but is permeable to hot steam used to sterilize the needle unit in the magazine.

When the needle unit is going to be used, the membrane 17 is removed and the needle receiving part of a syringe is inserted into the open end of the sleeve 6

and moved into this sleeve until the protrusions 7 engages the recesses in the needle receiving part of the syringe. When the syringe is retracted the needle unit will follow this syringe due to the snap connection between this needle unit and the syringe. The protrusion 8 of the needle hub may pass the tongues of the locking sleeve as these tongues are passed in a direction allowing them to be further deflected. When the needle unit is removed from the magazine the tongues will due to their flexibility return to a position with their free ends defining a circle having a diameter smaller than the diameter of the needle hub.

When after use the needle hub mounted on the syringe is reinserted in the magazine the needle hub will abut the tongues and deflect them to an oblique position with their free ends pointing away from the access opening of the magazine. During further insertion of the needle unit the protrusion 8 of this unit may pass the tongues and after this passing the needle unit is locked in the magazine as a retraction will cause the free ends of the tongues to abut against the edge 9 and consequently the force exerted on the tongues during a retraction of the needle unit is not a deflecting one but a force in the longitudinal direction of the tongues so that the tongues must be crumbled before the needle unit may be removed from the magazine. For such a crumbling a force is needed which far exceeds the force needed to release the snap connection between the needle unit and the syringe, and consequently the needle unit will remain in the magazine when the syringe is retracted.

In the shown embodiment the needle unit was designed for use with the magazine by having an edge 9 facing the access opening of the magazine. This edge 9 is provided on a circumferential protrusion 8 of the needle unit. The edge may alternatively be provided as end surfaces of circumferentially spaced ribs on the outer surface of the sleeve 6 or as an edge of a circumferential recess in this outer surface.

In a more universal embodiment of the magazine no special designed needle unit is demanded. In such an embodiment tongues 14 having a sharp free end are provided as radially inward pointing tongues of metal or a hard plastic. The sleeve

13 and the tongues 14 are preferably moulded as one integral part. However, if different materials are used for the sleeve and the tongues, a flat ring 18 is provided with radial inward pointing tongues 14 as shown in figure 5. This ring has a diameter corresponding to the diameter of the access opening of the magazine. When the needle unit is positioned in the magazine the ring is placed in the gap between the needle unit and the wall of the compartment 12 so that the needle hub deflects the tongues 14 to an oblique position with their free ends abutting the outer surface of the sleeve 6. The ring 18 is placed so it abuts a shoulder formed by ends of the needle hub supporting ribs 21 and is secured in this position by a sleeve 20 inserted from the access opening of the magazine as shown i figure 4. During the first removal and the reinsertion of the needle hub the tongues 14 will function in the same way as the tongues 14 in figure 1 - 3, but if an attempt is made to remove the reinserted needle unit from the magazine the sharp free end of the tongues will cut into the surface of the needle hub and provide a detent against removal of the needle unit. This function is not depending on the needle unit design and the protrusions 8 shown in figure 4 are not actually needed.

Figure 6 shows an exploded view of a magazine with a needle unit. In this figure it is seen that some of the tongues in the locking sleeve are replaced by axial guiding ribs 22 which abutting an outer circumferential surface of the needle unit contribute to the centering of the needle unit in the magazine.

Claims

1. A magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a mainly cylindric outer wall, characterized in that the magazine has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

2. A magazine according to claim 1, characterized in that the free end of the protrusions abutting the cylindric part of the needle unit are sharpened.

3. A magazine according to claim 2, characterized in that the protrusions are provided as radially inward extending tongues in a metal ring fixed at the inner wall of the compartment of the magazine.

4. A magazine according to anyone of the claims 1 - 3, characterized in that the protrusions are provided on the inner surface of a sleeve which as a lining is inserted and secured in the compartment.

5. A needle hub for use in a magazine according to the claims 1-4, characterized in that on the mainly cylindric outer wall of the needle unit at least one circumferential edge is provided facing the open end of the sleeve.

6. A needle hub according to claim 5, characterized in that the edge is defined by the ends of a number of circumferential spaced axial ribs on the cylindric outer wall of the needle unit.

7. A needle hub according to claim 5, characterized in that the edge is provided by the cylindric outer wall of the needle unit being provided with a circumferential ring shaped protrusion.

8. A needle hub according to claim 5, characterized in that the edge is provided as an edge of a circumferential recess in the cylindric outer wall of the needle hub.

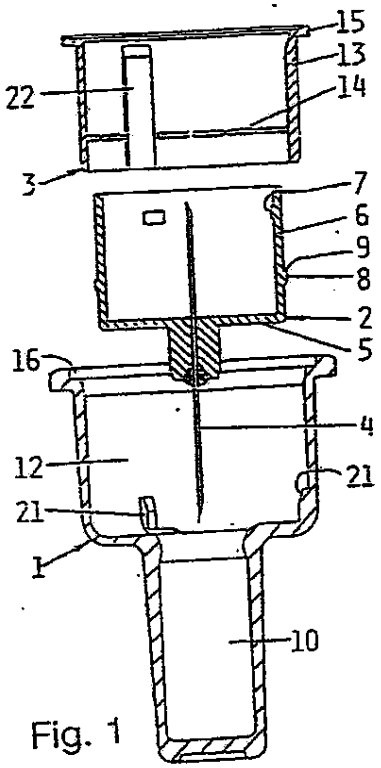

Fig. 1

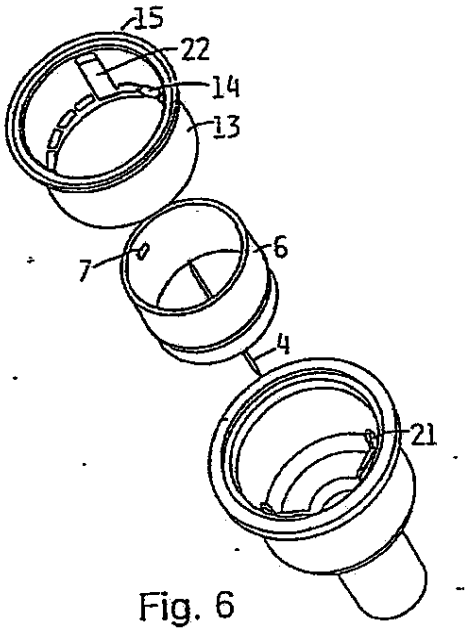

Fig. 6

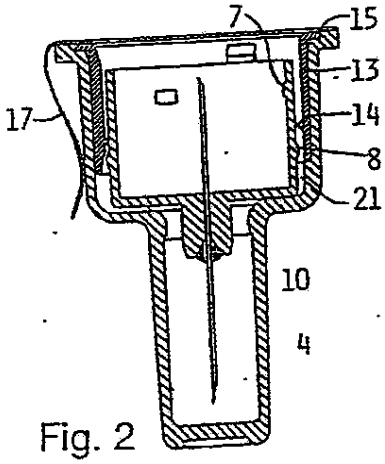

Fig. 2

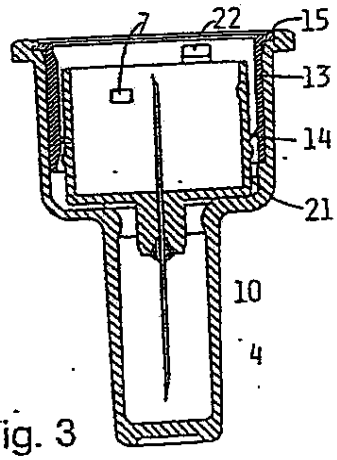

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 95/00306

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/32
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8200412 A1 (ELISHA, BENJAMIN), 18 February 1982 (18.02.82), page 4, line 18 - line 27, figure 2	1-4
X	figure 3	5,7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 1995	10-11-1995
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INTERNATIONAL SEARCH REPORT
Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 8200412	18/02/82	NONE	

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Avec rapport de recherche internationale.

(54) Title: DISPENSING DEVICE WITH SAFE OPERATION CONTROL AND REFILL FOR SAME

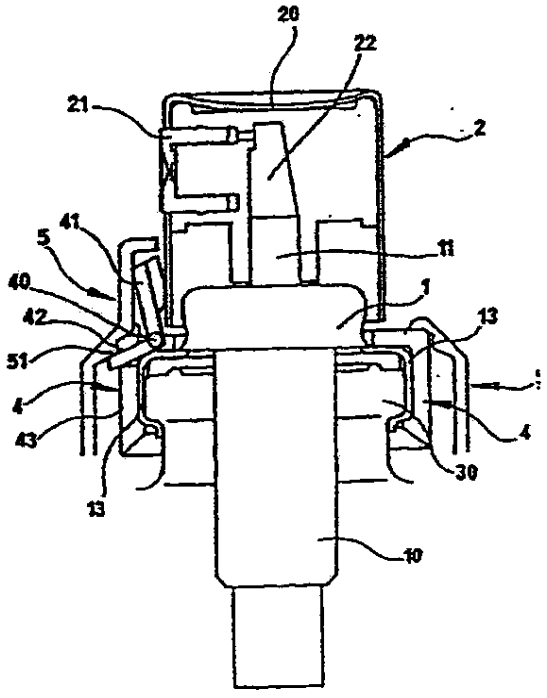
(54) Titre: DISPOSITIF DE DISTRIBUTION A SECURITE D'ACTIONNEMENT ET RECHARGE D'UN TEL DISPOSITIF

(57) Abstract

The invention discloses a dispensing device for a fluid product comprising a dispensing unit (1) provided with an axially movable control head (2) and a reservoir (3) containing the fluid to be dispensed, the said dispensing unit (1) being fixed on the reservoir (3), characterised in that the device further comprises means (4) for blocking any axial movement of the control head (2), and unlocking means (5) for engaging to the said blocking means (4) to cancel the action of the said blocking means (4) on the control head (2) and thus allow the axial movement of the said control head (2).

(57) Abrégé

Dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que le dispositif comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), et des moyens de déverrouillage (5) destinés à être mis en prise avec les moyens de blocage (4) pour effacer l'action desdits moyens de blocage (4) sur la tête d'actionnement (2) et ainsi permettre le déplacement axial de ladite tête d'actionnement (2).



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Dispositif de distribution à sécurité d'actionnement et recharge d'un tel dispositif.

La présente invention concerne un dispositif de distribution à sécurité d'actionnement ainsi qu'une recharge d'un tel dispositif. L'invention s'applique plus particulièrement au domaine de la parfumerie où le conditionnement du produit joue un rôle esthétique important. Le conditionnement peut représenter une certaine valeur et il est alors avantageux de pouvoir le rentabiliser. Des recharges peuvent alors être spécialement prévues pour ce type de conditionnement. L'application de l'invention dans le cadre d'un conditionnement réutilisable n'est qu'une mise en oeuvre préférentielle ; bien entendu, le dispositif de distribution à sécurité d'actionnement de l'invention peut être utilisé dans bien d'autres domaines tel que la cosmétique, la pharmacie, l'alimentation, la droguerie etc., sans application à un conditionnement réutilisable.

Il est déjà connu d'équiper certains dispositifs de distribution du type réservoir ou flacon muni d'un organe de distribution tel une pompe ou une valve, de sécurités d'actionnement ou de garanties de premier usage, afin d'assurer à l'utilisateur la primeur d'utilisation du dispositif. Ces sécurités ou garanties se présentent souvent sous la forme de bandes arrachables ou frangibles reliées à la tête d'actionnement du dispositif pour empêcher son actionnement. Une fois la bande arrachée ou détruite, la tête d'actionnement peut se déplacer axialement et distribuer le produit. Ce genre de sécurité ou garantie est basé sur le principe de l'immobilisation de la tête d'actionnement grâce à un élément à retirer ou à détruire.

L'arrachement ou la destruction de la bande nécessite une certaine force de traction qui peut parfois conduire au déchirement de la bande elle-même ; une partie de la bande reste alors en place, et il est difficile de la retirer complètement. En outre, la bande retirée constitue un déchet de petite taille dont il faut se débarrasser tout de même. Un autre inconvénient provient du fait que ce type de sécurité est irréversible, en ce sens que la bande ne peut plus être remise en place pour empêcher l'actionnement de la tête.

Un problème à la base de la présente invention est de réaliser un dispositif de distribution pourvu d'une sécurité d'actionnement fiable, non destructive, c'est-à-dire réversible, et dont la mise hors fonction s'effectue sans nécessiter une force particulière.

On connait déjà du document US-3 885 717 une sécurité à l'usage des enfants pour des bombes aérosols. La tête d'actionnement de la valve est pourvue de part et d'autre de pattes élastiques qui s'étendent vers le bas et dont les extrémités sont dotées de crochets qui viennent en prise sous la tête d'actionnement. Les pattes définissent ainsi ensemble un passage que le doigt doit obligatoirement emprunter pour accéder à la tête d'actionnement. Le doigt étant plus large que celui d'un enfant, seul le doigt d'un adulte est apte à s'engager dans le passage formé par les pattes élastiques en les repoussant de manière à dégager les crochets d'en dessous de la tête. Dans cette sécurité, le déverrouillage est effectué par le doigt de l'utilisateur et par conséquent tout adulte peut déverrouiller la bombe. Il ne s'agit donc pas d'une sécurité totale, mais uniquement sélective à l'égard des enfants. D'autre part, la largeur des doigts chez les adultes est très variable, de sorte que cette sécurité n'assure même pas la possibilité d'utilisation pour tous les adultes.

La présente invention a pour but de remédier à ces inconvénients en définisant une sécurité dite de premier usage non sélective dont le déverrouillage ne dépend pas de la nature de l'utilisateur.

Pour ce faire, il est prévu un dispositif de distribution de produit fluide comprenant un organe de distribution doté d'une tête d'actionnement déplacable axialement et d'un réservoir contenant le produit fluide à distribuer, ledit organe de distribution étant fixé sur le réservoir, caractérisé en ce que le dispositif comprend en outre des moyens de blocage pour empêcher tout déplacement axial de la tête d'actionnement, et des moyens de déverrouillage pour effacer l'action desdits moyens de blocage sur la tête d'actionnement et ainsi permettre le déplacement axial de ladite tête d'actionnement. Les moyens de déverrouillage assurent la mise hors fonction des moyens de blocage qui restent en place sur le dispositif.

Avantageusement, les moyens de blocage comprennent au moins un élément de blocage disposé dans le chemin de déplacement axial de la tête d'actionnement, ledit élément de blocage étant écarté du chemin de déplacement axial de la tête d'actionnement par lesdits moyens de déverrouillage.

Selon une forme de réalisation, ledit au moins un élément de blocage est monté pivotant et comprend une surface de came, lesdits moyens de déverrouillage venant en prise avec ladite surface de came pour écarter par pivotement ledit élément de blocage hors du chemin de déplacement axial de la tête d'actionnement.

De préférence, les moyens de blocage comprennent plusieurs éléments de blocage répartis à espacement angulaire régulier tout autour de la tête d'actionnement.

Alors que la mise hors fonction de la sécurité de l'art antérieur constituée d'une bande est simplement

réalisée par son arrachement ou sa destruction, dans la présente invention, les éléments de blocage sont écartés par pivotement sans destruction de sorte que le retrait des moyens de déverrouillage permet à nouveau aux éléments de blocage de reprendre leur position initiale dans le chemin de déplacement de la tête ; ceci assure la réversibilité de la sécurité d'actionnement.

Selon une forme pratique, les moyens de blocage se présentent dans la forme d'une bague de blocage montée fixement sur l'organe de distribution ou le réservoir, ladite bague de blocage étant pourvue à son extrémité supérieure desdits éléments de blocage pivotants, lesdits moyens de déverrouillage se présentant sous la forme d'une bague de déverrouillage rapportée sur la bague de blocage en sollicitant les éléments de blocage par pivotement vers l'extérieur hors du chemin de déplacement de la tête d'actionnement.

Les moyens de déverrouillage sont rapportés sur les moyens de blocage avec lesquels ils viennent ainsi en prise pour effacer leur action. De plus, les moyens de déverrouillage agissent sur les moyens de blocage indépendamment de l'actionnement de la tête d'actionnement. Le déverrouillage n'est pas effectué par le doigt de l'utilisateur comme dans le document US-3 885 717 mais par un organe rapporté qui n'agit sur la tête d'actionnement.

Selon une caractéristique très avantageuse de la présente invention, le dispositif comprend en outre un étui dans lequel le réservoir est introduit, les moyens de déverrouillage connectant ledit étui de manière démontable, de sorte que le réservoir équipé de son organe de distribution peut être introduit et extrait de l'étui en tant que recharge, la connexion des moyens de déverrouillage sur l'étui mettant lesdits moyens de

déverrouillage en prise avec les moyens de blocage pour les déverrouiller.

Dans cette application préférentielle de l'invention, le réservoir équipé de son organe de distribution constitue une recharge pour un étui dont la partie supérieure de fermeture est constituée par les moyens de déverrouillage qui opèrent à la fois le déverrouillage des moyens de blocage et la fermeture de l'étui. Cette forme de réalisation est particulièrement avantageuse, car l'utilisateur n'a même pas besoin d'effectuer une opération particulière pour effacer l'action des moyens de blocage qui se fait automatiquement lors de l'encliquetage des moyens de déverrouillage sur l'étui.

Ainsi, il n'est même pas nécessaire d'informer l'utilisateur que la recharge incorpore une sécurité d'actionnement. De plus, si l'utilisateur souhaite bloquer l'actionnement du dispositif pendant un certain temps, il lui suffit de retirer légèrement les moyens de déverrouillage et les éléments de blocage reprendront leur place initiale sous la tête d'actionnement.

L'invention définit également une recharge de dispositif de distribution de produit fluide comprenant un organe de distribution doté d'une tête d'actionnement déplaçable axialement et d'un réservoir contenant le produit fluide à distribuer, ledit organe de distribution étant fixé sur le réservoir, caractérisé en ce que la recharge comprend en outre des moyens de blocage pour empêcher tout déplacement axial de la tête d'actionnement, lesdits moyens de blocage étant destinés à être déverrouillés à l'aide de moyens de déverrouillage faisant partie d'un ensemble de conditionnement destiné à recevoir ladite recharge. La recharge peut être achetée dans le commerce, équipée de sa sécurité d'actionnement, ce qui assure la primeur d'utilisation. L'ensemble de conditionnement est réutilisable et comprend un étui et

les moyens de déverrouillage qui viennent former l'étui en ne laissant passer que la tête d'actionnement.

L'invention sera maintenant décrite plus amplement en référence aux dessins joints, donnant à titre d'exemple non limitatif plusieurs modes de réalisation de l'invention.

Sur les dessins :

- la figure 1 représente la partie supérieure d'un dispositif de distribution selon l'invention avec les moyens de blocage en position de blocage, des moyens de déverrouillage étant omis,
- la figure 2 représente un dispositif de distribution de la figure 1 avec les moyens de déverrouillage en prise avec les moyens de blocage de manière à permettre le déplacement de la tête d'actionnement,
- la figure 3 représente une forme préférentielle de réalisation d'un dispositif de distribution selon l'invention, les moyens de blocage étant en position de blocage et les moyens de déverrouillage étant omis,
- la figure 4 est une vue du dispositif de distribution de la figure 3 avec les moyens de déverrouillage en prise avec les moyens de blocage de manière à libérer la tête d'actionnement dans son déplacement axial, et
- la figure 5 est une vue agrandie en coupe des moyens de blocage utilisé dans le dispositif de distribution représenté sur les figures 3 et 4.

En se référant d'abord aux figures 1 et 2, on voit que le dispositif de distribution selon cette première forme de réalisation ne représente que la partie supérieure du dispositif, seul le goulot 30 du réservoir étant représenté. Outre le réservoir qui peut être rigide ou souple, en matière plastique en verre ou en métal, le dispositif de distribution de l'invention comprend un organe de distribution désigné dans son ensemble par la référence numérique 1. Cet organe de distribution 1 qui

peut être une pompe ou une valve, comprend un corps de pompe 10 engagé dans le goulot 30 du réservoir. L'organe de distribution est serti par la partie supérieure de son corps 10 sur le goulot 30 à l'aide d'un sertissage 13. De manière classique, un joint peut être interposé entre le goulot 30 et le sertissage 13 pour assurer l'étanchéité du dispositif au niveau du goulot du réservoir. L'organe de distribution comprend en outre une tige d'actionnement 11 qui est montée coulissante dans le corps 10 de l'organe de distribution 1. La tige d'actionnement 11 est creuse et constitue ainsi un canal de refoulement du produit fluide mis sous pression dans le corps 10. Pour l'actionnement de la tige 11, il est prévu une tête d'actionnement désignée dans son ensemble par la référence numérique 2. La tête d'actionnement 2 comprend un canal interne 22 en communication avec l'intérieur de la tige d'actionnement 11 ainsi qu'avec un gicleur 21 destiné à pulvériser le produit fluide en fines gouttelettes. La tête d'actionnement 2 comprend également une surface de pression 20 adaptée à l'application d'un doigt par exemple. Une pression sur la surface 20 de la tête d'actionnement 2 amène la tête et la tige 11 à se déplacer axialement, comme on peut le voir sur les figures 1 et 2. Dans le cas d'une pompe, l'enfoncement de la tige 11 a pour effet de mettre la chambre de pompe comprise dans le corps de pompe 10 sous pression jusqu'à ce que le clapet de sortie de la pompe s'ouvre et refoule la dose de produit fluide à travers l'intérieur creux de la tige d'actionnement 11 jusqu'au gicleur 21 où la dose de produit fluide est pulvérisée. Dans le cas d'une valve, l'enfoncement de la tige de soupape 11 a pour effet de mettre en communication fluide l'intérieur du réservoir ou une partie de celui-ci avec l'extérieur à travers l'intérieur creux de la tige de soupape 11 jusqu'au gicleur 21 où le produit fluide est pulvérisé. Dans les

deux cas, qu'il s'agisse d'une pompe ou d'une valve, la distribution du produit fluide est réalisé grâce au déplacement axial de la tige d'actionnement 11 surmontée de son bouton poussoir 2 incorporant le gicleur 21.

Cette conception générale du dispositif de distribution selon l'invention est commune à toute les formes de réalisation décrite.

En se référant maintenant plus particulièrement à la figure 1, on voit que le goulot 30 du réservoir, ou plus précisément le sertissage 13 de l'organe de distribution, est recouvert par une pièce désignée dans son ensemble par la référence numérique 4 qui sert de moyen de blocage pour la tête d'actionnement 2. Cette pièce 4 réalisant un moyen de blocage comprenant une bague de blocage formée avec des pattes d'encliquetage 43 terminée par des dents d'encliquetage 46 qui sont en prise avec le goulot 30 du réservoir. Les pattes d'encliquetage 43 munies de leurs dents 46 permettent une fixation solide et stable de la pièce 4 sur le goulot 30. La bague de blocage 4 s'étend jusqu'au dessus du goulot 30 où elle est pourvue d'éléments de blocage 41 qui sont disposés dans le chemin de déplacement axial de la tête d'actionnement 2 pour bloquer la tête d'actionnement 2 en position de repos. Les éléments de blocage 41 sont répartis tout autour de la bague de blocage 4 dans le chemin de déplacement axial de la tête d'actionnement 2. Les éléments de blocage 41 peuvent au nombre de trois ou de six mais il est également envisageable de ne prévoir qu'un seul élément de blocage 41 sur la bague de blocage 4. Les éléments de blocage 41 sont montés pivotants sur la bague 4 autour d'un axe de pivotement 40. Pour permettre le pivotement des éléments de blocage 41, il est prévu une surface de came 42 qui est reliée à l'élément de blocage 41 de manière rigide de sorte qu'une pression exercée sur la surface de came 42 provoque le pivotement de l'élément de blocage 41 autour

de l'axe de pivotement 40. Comme on peut le voir sur la figure 1, les axes de pivotement 40 s'étendent de manière tangentielle à la bague de blocage 4, de sorte que la direction de pivotement de l'élément de blocage 41 s'étend radialement par rapport à la tige d'actionnement 11. Dans la position de repos de la bague de blocage 4, les éléments de blocage 41 sont disposés dans le chemin de déplacement axial de la tête d'actionnement 2. Afin d'assurer que les éléments de blocage sont correctement disposés en dessous de la tête d'actionnement 2, les éléments de blocage 41 sont pourvu d'un épaississement 410, qui augmente considérablement la surface de butée de l'extrémité inférieure de la tête d'actionnement 2 sur l'extrémité supérieure des éléments de blocage 41. Ainsi, grâce à l'interposition des éléments de blocage 41 en dessous de la tête d'actionnement 2, tout déplacement axial de la tête de et par conséquent de la tige d'actionnement 11, est empêché. Le dispositif de distribution ne peut alors pas être actionner de sorte qu'aucune dose de produit fluide ne peut être émise.

En se référant maintenant à la figure 2, il va être expliquer de quelle manière les éléments de blocage 41 sont déplacés hors du chemin de déplacement axial de la tête d'actionnement 2. Comme on peut le voir sur la partie gauche de la figure 2, les éléments de blocage 41 sont écartés hors du chemin de déplacement axial de la tête d'actionnement 2 à l'aide d'une bague de déverrouillage désignée dans son ensemble par la référence numérique 5. La bague de déverrouillage comprend une surface d'appui 51 qui coopère avec la surface de came 42 de l'élément de blocage 41 de manière à abaisser la surface de came 42. L'abaissement de la surface de came 42 provoque le pivotement de l'élément de blocage 41 vers l'extérieur en éloignement de la tige d'actionnement 11. La bague de déverrouillage 5 doit donc être emmanchée sur la bague de

blocage 4 jusqu'à ce que la surface d'appui 51 de la bague de déverrouillage 5 sollicite la surface de came 42 de l'élément de blocage 41 vers le bas. Le maintien en place de la bague de déverrouillage 5 peut être réalisée grâce à un encliquetage de la bague 5 sur la bague 4 ou sur une autre partie du réservoir. Ainsi, la mise en place de la bague de déverrouillage 5 sur la bague de blocage 4 a pour effet d'écarter les éléments de blocage 41 hors du chemin de déplacement axial de la tête d'actionnement 2. Comme visible sur la figure 2, la tête d'actionnement peut alors être déplacée vers le bas, ce qui a pour effet d'émettre du produit fluide par le gicleur 21.

Il est à noter que l'utilisation d'une bague de déverrouillage 5 pour effacer l'action des éléments de blocage préserve la réversibilité de la fonction de blocage des éléments de blocage 41 par simple retrait de la bague de déverrouillage. En effet en retirant la bague de déverrouillage 5, la surface de came 42 n'est plus sollicitée vers le bas par la surface d'appui 51 de la bague 5, ce qui a pour effet de faire pivoter les éléments de blocage 41 à nouveau dans le chemin de déplacement axial de la tête d'actionnement 2. Il est donc possible grâce à l'invention de remettre le dispositif de distribution à nouveau en sécurité par simple retrait de la bague de déverrouillage 5, ce qui n'était pas possible avec les dispositifs de sécurités ou de garanties de l'art antérieur qui impliquait une destruction des éléments de blocage.

En référence aux figures 3 et 4, il sera maintenant décrit un mode de réalisation et d'application préférentiel de la présente invention. Le caractère préférentiel tient plus à la mise en application du dispositif de distribution qu'à sa forme de réalisation particulière. Dans cette forme de réalisation et d'application, l'ensemble constitué du réservoir 3 et de

son organe de distribution associé 1 surmonté de la tête d'actionnement 2 constitue une recharge destinée à être placée dans un ensemble de conditionnement constitué d'un étui 7 enveloppant partiellement le réservoir 3, d'un manchon de liaison 6 et de la bague de déverrouillage 5. La recharge pourra être achetée dans le commerce déjà équipé de sa bague de blocage 4 assurant la sécurité de premier usage, afin de garantir la primeur d'utilisation à l'acheteur du produit. Tout comme la bague de blocage de la forme de réalisation des figures 1 et 2, la bague de blocage de cette forme de réalisation préférentielle est monté fixement sur un bossage périphérique annulaire réalisé par le goulot du réservoir 3 recouvert par le sertissage 13 de l'organe de distribution 1. Dans son état encore non monté dans l'ensemble de conditionnement, et disponible tel quel dans le commerce la recharge ne peut pas être actionnée en raison de l'interposition des éléments de blocage 41 en dessous de la tête d'actionnement 2.

En se référant maintenant à la figure 4, la recharge est représentée introduite dans un ensemble de condition dont la partie supérieure de fermeture est réalisée par la bague de déverrouillage 5. La bague de déverrouillage 5, comme dans le mode de réalisation représenté sur les figures 1 et 2, sollicite les éléments de blocage 41 par pivotement vers l'extérieur hors du chemin de déplacement axial de la tête d'actionnement 2. Le pivotement vers l'extérieur des éléments de blocage 41 est réalisé par appui de la bague de déverrouillage 5 sur les surfaces de came 42 solidaires des éléments de blocage 41.

Le détail de réalisation de la bague de blocage 4 sera décrit plus précisément en référence à la figure 5 ci-après. La bague de déverrouillage 5 coopère donc d'une part avec les surfaces de came 42 des éléments de blocage 41 ainsi qu'avec un manchon de transition 6 qui lui est

encliqueté dans l'extrémité supérieure ouverture de l'étui 7. La connexion de la bague de déverrouillage 5 sur l'extrémité supérieure du manchon de transition 7 peut être du type encliquetage, emmanchage en force ou même vissage. L'ensemble de condition réalisé par les éléments constitutifs 5, 6 et 7 recouvrent la totalité de la recharge à l'exception de la tête d'actionnement 2 qui doit rester accessible en vue de son actionnement.

Dans cette application en tant que recharge pour un ensemble de conditionnement réutilisable, l'effacement des éléments de blocage 42 est réalisé de manière automatique lors de la fermeture de l'ensemble de conditionnement en rapportant simplement la bague de déverrouillage sur le manchon de transition 6. Ainsi, en une seule opération l'ensemble de condition est reconstitué et la sécurité d'actionnement est effacée.

La figure 5 représente une section agrandie de la bague de blocage utilisée dans la recharge représentée sur les figures 3 et 4. La bague de blocage 4 est formée avec les pattes d'encliquetage 43 pourvues d'un évidemment périphérique annulaire 46 destiné à recevoir le bossage périphérique formé par le goulot 30 du récipient 3. Les pattes d'encliquetage 43 sont surmontées par les éléments de blocage 41 pourvus de leurs surfaces de came 42. Alors que dans la forme de réalisation des figures 1 et 2 le pivotement des éléments de blocage 4 était réalisé grâce à un axe de pivotement 40, dans cette forme de réalisation, le pivotement des éléments de blocage 41 est assuré par un pont de matière 45 qui relie les éléments de blocage 41 au restant de la bague. Les ponts de matière présentent une section réduite de manière à créer une zone de faiblesse définissant un point d'articulation. Le nombre d'élément de blocage 41 répartie tout autour de la bague de blocage peut être variable, mais en général ils seront au nombre de 3 à 6.

Revendications :

1.- Dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que le dispositif comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), et des moyens de déverrouillage (5) pour effacer l'action desdits moyens de blocage (4) sur la tête d'actionnement (2) et ainsi permettre le déplacement axial de ladite tête d'actionnement (2).

2.- Dispositif de distribution selon la revendication 1 dans lequel les moyens de blocage (4) comprennent au moins un élément de blocage (41) disposé dans le chemin de déplacement axial de la tête d'actionnement (2), ledit élément de blocage (41) étant écarté du chemin de déplacement axial de la tête d'actionnement (2) par lesdits moyens de déverrouillage (5).

3.- Dispositif de distribution selon la revendication 2 dans lequel ledit au moins un élément de blocage (41) est monté pivotant et comprend une surface de came (42), lesdits moyens de déverrouillage (5) venant en prise avec ladite surface de came (42) pour écarter par pivotement ledit élément de blocage (41) hors du chemin de déplacement axial de la tête d'actionnement (2).

4.- Dispositif de distribution selon les revendications 1 ou 2 dans lequel les moyens de blocage (4) comprennent plusieurs éléments de blocage (41) répartis à espacement angulaire régulier tout autour de la tête d'actionnement (2).

5.- Dispositif de distribution selon la revendication 4 dans lequel les moyens de blocage se présentent dans la

forme d'une bague de blocage (4) montée fixement sur l'organe de distribution (1) ou le réservoir (3), ladite bague de blocage (4) étant pourvue à son extrémité supérieure desdits éléments de blocage pivotants (41), lesdits moyens de déverrouillage se présentant sous la forme d'une bague de déverrouillage (5) rapportée sur la bague de blocage (4) en sollicitant les éléments de blocage (41) par pivotement vers l'extérieur hors du chemin de déplacement de la tête d'actionnement (2).

6.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel les moyens de déverrouillage sont rapportés sur les moyens de blocage avec lesquels ils viennent ainsi en prise pour effacer leur action.

7.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel les moyens de déverrouillage agissent sur les moyens de blocage indépendamment de l'actionnement de la tête d'actionnement.

8.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel le dispositif comprend en outre un étui (7) dans lequel le réservoir (3) est introduit, les moyens de déverrouillage (5) connectant ledit étui (7) de manière démontable, de sorte que le réservoir (3) équipé de son organe de distribution (1) peut être introduit et extrait de l'étui (7) en tant que recharge, la connexion des moyens de déverrouillage (5) sur l'étui (7) mettant lesdits moyens de déverrouillage (5) en prise avec les moyens de blocage (4) pour les déverrouiller.

9.- Dispositif de distribution selon la revendication 8, dans lequel les moyens de déverrouillage (5) sont encliquetés sur l'étui (7), l'encliquetage opérant simultanément le déverrouillage des moyens de blocage (4).

10.- Recharge de dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que la recharge comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), lesdits moyens de blocage (4) étant destinés à être déverrouillés à l'aide de moyens de déverrouillage (5) faisant partie d'un ensemble de conditionnement destiné à recevoir ladite recharge.

1/2

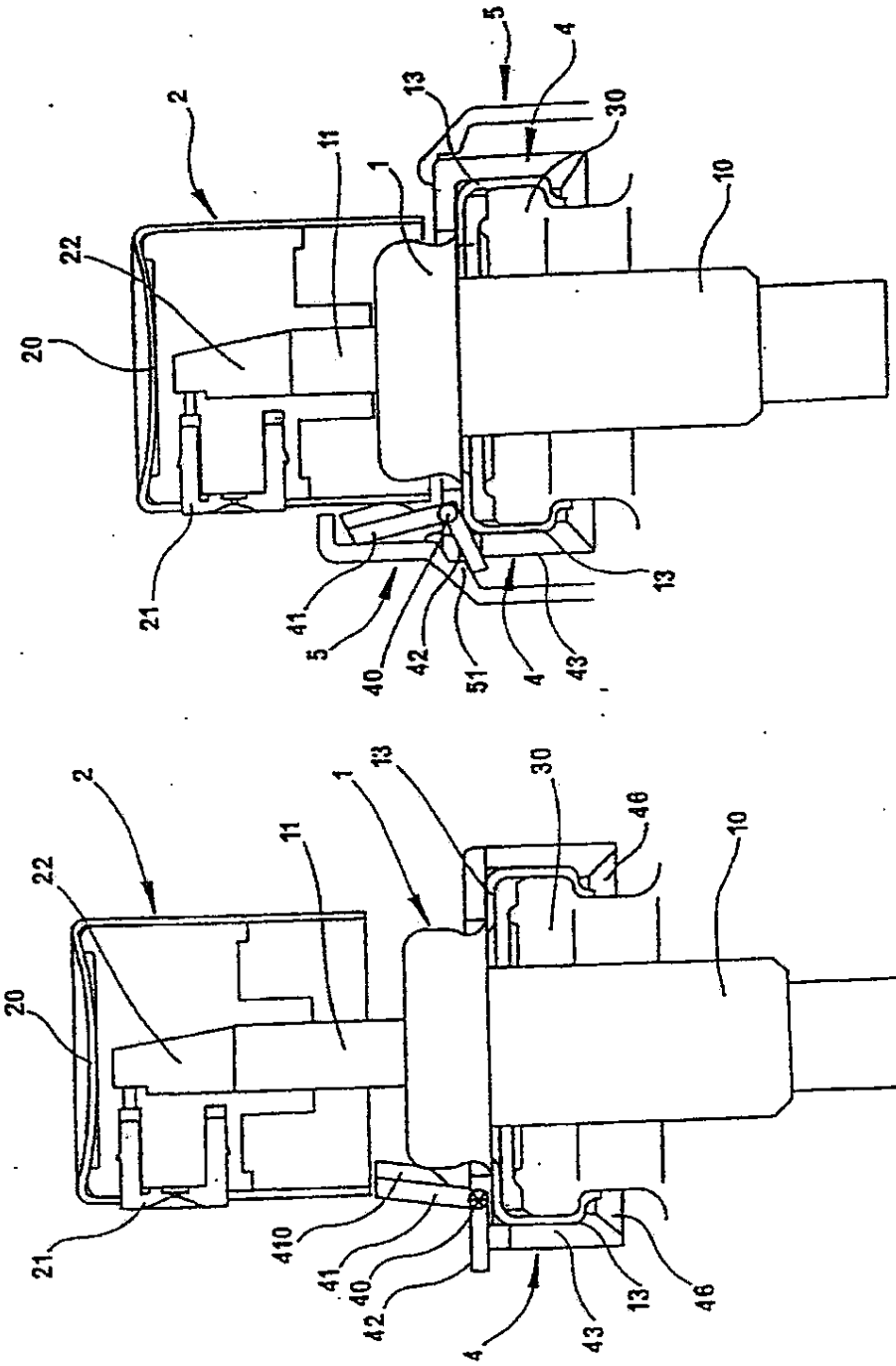
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FIG. 1

2/2

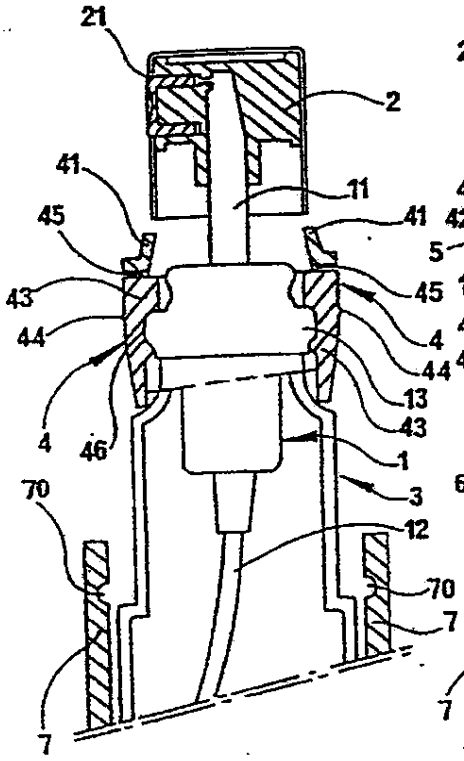

FIG.3

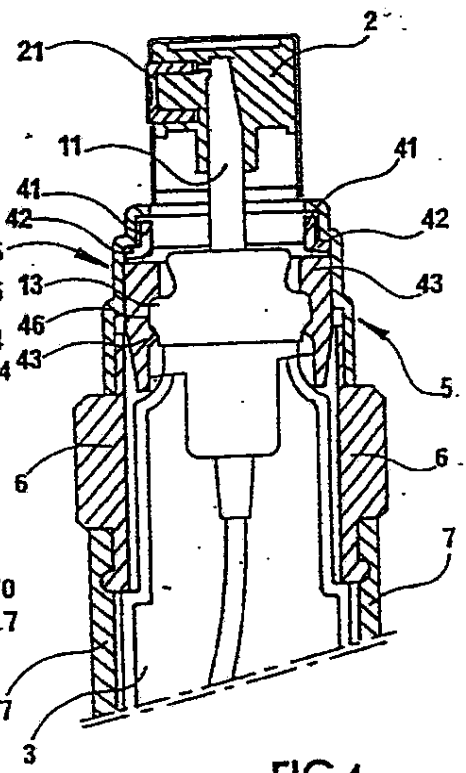

FIG.4

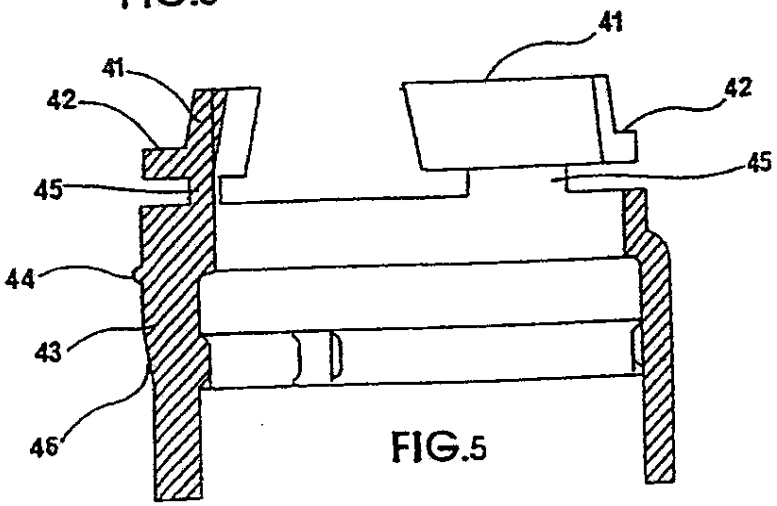

FIG.5

INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/FR 97/01064

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D83/14 B05B11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B65D B05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 885 717 A (EWALD RONALD F) 27 May 1975 see column 5, line 37 - column 5, line 53 see figures 5,6	1,10
A	US 3 606 106 A (YUHAS EDWARD R) 20 September 1971 see column 1, line 33 - column 2, line 23 see figures 1,2	1,10
A	EP 0 168 285 A (TELEPLASTICS IND) 15 January 1986 see abstract see figures 4,4A	1,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 September 1997	10.09.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Farizon, P

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ...ional Application No
PCT/FR 97/01864

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3885717 A	27-05-75	CA 1014121 A	19-07-77
		DE 2418720 A	31-10-74
		FR 2226330 A	15-11-74
		GB 1442607 A	14-07-76
		GB 1442606 A	14-07-76
		NL 7400458 A	22-10-74
		US 4017009 A	12-04-77
		US 3786968 A	22-01-74
US 3606106 A	20-09-71	NONE	
EP 0168285 A	15-01-86	FR 2565799 A	20-12-85
		DE 3562007 A	05-05-88
		US 4676408 A	30-06-87

RAPPORT DE RECHERCHE INTERNATIONALE

Dem. internationale No
PCT/FR 97/01064

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 6 B65D83/14 B05B11/00

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 6 B65D B05B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela est réalisable, termes de recherche utilisés)

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US 3 885 717 A (EWALD RONALD F) 27 mai 1975 voir colonne 5, ligne 37 - colonne 5, ligne 53 voir figures 5,6	1,10
A	US 3 606 106 A (YUHAS EDWARD R) 20 septembre 1971 voir colonne 1, ligne 33 - colonne 2, ligne 23 voir figures 1,2	1,10
A	EP 0 168 285 A (TELEPLASTICS IND) 15 janvier 1986 voir abrégé voir figures 4,4A	1,10

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

* Catégories spéciales de documents cités:

"A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent

"E" document antérieur, mais publié à la date de dépôt international ou après cette date

"L" document pouvant jeter un doute sur une revendication de priorité ou cité pour déterminer la date de publication d'une autre citation ou pour une raison spéciale (telle qu'indiquée)

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Renseignements relatifs aux membres de familles de brevets

Demande internationale No
PCT/FR 97/01864

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
US 3885717 A	27-05-75	CA 1014121 A	19-07-77
		DE 2418720 A	31-10-74
		FR 2226330 A	15-11-74
		GB 1442607 A	14-07-76
		GB 1442606 A	14-07-76
		NL 7400450 A	22-10-74
		US 4017009 A	12-04-77
		US 3786968 A	22-01-74
US 3606106 A	20-09-71	AUCUN	
EP 0168285 A	15-01-86	FR 2565799 A	20-12-85
		DE 3562007 A	05-05-88
		US 4676408 A	30-06-87

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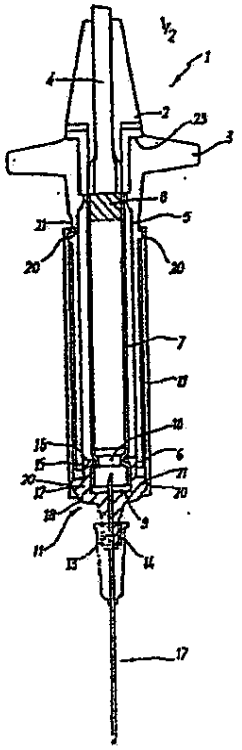
(54) Title: SYRINGES

(57) Abstract

A syringe has a drug-containing cartridge (7) with a bung (8) at one end which is engaged by a plunger (4), and a membrane (9) at its other end which is penetrated by a needle. A connecting structure (11) is connected to (or is formed integrally with) the needle (17) and fits onto the forward end of the cartridge (7) and the syringe. After use the cartridge (7), the connecting structure (11) and the needle (17) can be disposed together. A sleeve (19) is slidably mounted on the structure (11) and can be moved to sheath the needle (17).



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SYRINGES

This invention relates to syringes.

A conventional syringe, e.g. as used by a dentist to administer anaesthetic, has a barrel with a plunger mechanism at one end and a threaded connector for a needle at the opposite end. A drug-containing glass cartridge is inserted into the barrel, the needle is screwed onto the connector so that it penetrates a seal at the forward end of the cartridge, and the plunger mechanism is operated to engage a bung at the rearward end of the cartridge and thereby expel the drug through the needle. After use, the needle and cartridge are removed and discarded.

In order to minimise contamination problems, European Application EP 0394295-A describes a syringe in which, in place of the above mentioned cartridge, there is a drug-containing housing which is attached directly to the needle at one end and to the plunger mechanism at the other end. After use the entire housing, including the needle, is detached from the plunger mechanism and discarded thereby avoiding the need to sterilise the barrel and needle connector of the conventional syringe.

Whilst this arrangement provides an effective solution to contamination problems, it is necessary for the specially-constructed detachable housing to be pre-filled with the drug which can be inconvenient from a manufacturing point of view.

An object of the present invention is to provide a disposable syringe housing which is convenient to manufacture.

According to one aspect of the invention therefore there is provided a detachable housing for a syringe comprising a drug-containing cartridge having a bung at one end and a penetrable member at the other end, the cartridge being adapted for connection to a needle at the said other end, such that the needle penetrates the penetrable member, and being adapted for connection to a plunger mechanism at the said one end, so that the bung can be moved down the cartridge to expel the drug through the needle, characterised in that the cartridge is provided with at least one separate structure attachable relative thereto, said structure being adapted for the said connection of the cartridge to the needle and providing means for releasable connection to the plunger mechanism, whereby the housing comprising the cartridge, the (or each) said structure, and the needle can be detached from the plunger mechanism for disposal together.

With this arrangement the advantages of disposability can be attained with an arrangement which is particularly simple and convenient to manufacture in so far as it involves the use of a simple drug-containing cartridge which may be of the kind used with conventional syringes.

Most preferably there is one said structure which is attachable to the said other end of the cartridge and which is adapted for connection to the needle and which provides the means for connection to the plunger mechanism.

Thus, and in accordance with a second aspect of the present invention there is provided a structure for attachment to a drug-containing

cartridge of a syringe, which cartridge has a bung at a rearward end and a penetrable membrane at a forward end, said structure being adapted for attachment to a needle and having means for attachment relative to the forward end of the cartridge, and means for attachment to a plunger mechanism.

The means for attachment to the cartridge may comprise a clip or constriction or the like which fits around a neck at the forward end of the cartridge, such neck being a feature of conventional cartridges.

The structure may be formed integrally with the needle or alternatively it may incorporate means for connection to the needle which may comprise a threaded boss or nipple.

The means for attachment to the plunger mechanism may comprise an outer peripheral retaining structure, such as a screw-thread, adapted to mate with a corresponding retaining structure at the end of a barrel extension on the plunger mechanism, which extension fits around the cartridge from the rearward to the forward end thereof.

The barrel extension may have a longitudinally movable sleeve which can be moved forwardly to sheath the needle after use. This sleeve may be removable and disposable with the housing.

If desired, provision may be made for aspiration, or slight suck back with the syringe so that it can be seen if a vein or atery has been penetrated, such penetration being revealed by suck back of blood.

Thus, the said structure may be provided with a spring arrangement

which acts to urge the cartridge in a direction away from the needle, in conjunction with a releasable retention device bearing on the top rim of the cartridge. The spring arrangement may comprise a projection engageable with the resilient penetrable member of the cartridge, or an interposed spring means.

The invention will now be described further by way of example only and with reference to the accompanying drawings in which:

Fig. 1 is an axial section of a syringe provided with one form of a disposable housing in accordance with the invention; and

Figs. 2 & 3 are enlarged axial sections of a bottom part of the arrangement of Fig. 1 showing alternative embodiments thereof.

Referring to Fig. 1, the syringe comprises a plunger mechanism 1 (e.g. of stainless steel) having a body part 2 with a finger grip 3, a plunger 4 slidable axially through a bore in the body 2, and a barrel extension 5 coaxial with the plunger 4. The barrel extension 5 may comprise a tube, or apertured tube, or tubular framework.

At its forward end, the tubular extension 5 has an internal screw-thread 6.

A conventional drug-containing cartridge 7 is used with the syringe, such cartridge comprising a glass tube with a bung 8 within one (rearward) end and a foil covered penetrable membrane 9 across the other (forward) end. The glass tube is shaped to provide a circumferential groove 10 defining a neck close to the forward end.

A connection structure 11 is attached to the forward end of the cartridge 7. This structure 11 comprises a plastics body of cup-shaped form with a cylindrical part 12 which is closed at one end and has a central axially projecting boss 13 on its outer face.

There is a narrow axial bore through the closed end and the boss 13. The boss 13 and the cylindrical part 12 both have external screw-threads 14, 15.

The cylindrical part 12 has an open end bounded by an inturned lip 16.

There is sufficient resilience in the lip 16 and/or the associated body of the connection structure 11 to enable the structure to be pushed over the forward end of the cartridge 7 so that the lip 16 springs into, or snap fits with, the groove 10 thereby to retain the structure 11 securely on the end of the cartridge 7.

With the connection structure 11 in position the cartridge 7 can be inserted into the barrel extension 5 and held securely in position by screwing the thread 15 of the cylindrical part 12 into engagement with the screw thread 6 at the end of the barrel extension 5.

A conventional needle 17 can then be screwed on to the boss 13 so that its rear end penetrates the membrane 9.

In this position the rearward end of the cartridge 7 is at the rearward end of the barrel extension 5 and the bung 8 is close to the end of the plunger 4.

The syringe can now be operated in the usual way to cause the bung 8 to be displaced down the cartridge 7 with the plunger 4 to expel drug through the needle 17.

After use, the connection structure 11 is unscrewed from the barrel extension 5 so that the cartridge 7, connection structure 11, and needle 17 can be removed and disposed together.

It will be seen that the cylindrical part 12 of the connection structure 11 has a lower, or forward portion 18 which is not threaded and which remains outside the barrel extension 5 to provide a convenient finger grip for screwing and unscrewing the structure 11. This portion 18 may be enlarged or shaped as desired to further facilitate gripping.

As shown in Fig. 1 a tubular sleeve 19 may be engaged around the connection structure 11, such sleeve 19 being movable axially between a rearward limit position (as shown) at which it overlies the barrel extension 5 and fully exposes the needle 17, and a forward limit position at which it covers the needle 17.

The sleeve 19 is removed and disposed together with cartridge 7 and needle 17 with the sleeve 19 covering the needle 17 to avoid needle stick injuries.

The sleeve 19 has inwardly directed recesses 20 at each end which snap fit with projections 21 on the structure 11 to hold the sleeve 19 in each limit position. Also, the sleeve 19 may be internally longitudinally grooved to accommodate the projections 21 whereby the sleeve 19 is free

to move axially but cannot rotate relative to the structure 11. The rotation of the structure 11 relative to barrel extension 5 can therefore be effected by rotation of the sleeve 19.

With the arrangement described above, full advantages of disposability can be attained using a conventional cartridge.

As shown in the modified embodiment of Fig. 2, the structure 11 has an upstanding small projection 22 which presses against the penetrable membrane 9 at the end of the cartridge. At the top end of the syringe there is a suitable structure (indicated diagrammatically at 23 in Fig. 1) which bears against the top rim of the cartridge and holds the projection 22 pressed firmly into the membrane 9.

If this top end bearing structure 23 is now released, and pressure is released from the plunger 4, the cartridge will move slightly upwards due to the resilience of the membrane 9. This gives a very small suck-back or aspiration effect through the needle.

This is useful e.g. in dentistry where an injection is being made into soft gum tissue and it is desired to avoid penetration of a vein or artery. If penetration of a vein or artery has occurred the aspiration will cause blood to flow back into the cartridge.

Other resilient or spring arrangements may be used to achieve aspiration. Thus, Fig. 3 shows a modification in which the structure 11 is formed integrally with the needle 17. Springy transverse projections 24 or fingers are incorporated for resilient engagement with the bottom of the

cartridge.

It is of course to be understood that the invention is not intended to be restricted to the details of the above embodiment which are described by way of example only.

Thus, for example, the embodiment of Fig. 1 utilises a conventional needle and therefore has said connection structure 11 which is separate from the needle and is adapted to be interconnected thereto by means of the threaded boss 13. However, if desired, and as shown in Fig. 3, the structure 11 may be formed integrally with the needle so that it is supplied together with the needle.

Where the structure 11 is interconnected by means of the threaded boss 13 with a conventional needle, the structure 11 may be supplied with the needle, or ready fitted on the end of the cartridge or as a separate part to be fitted to the needle and to the cartridge prior to use.

The syringe may be as described adapted for end loading of the cartridge. It is however also possible to use a conventional side-loading syringe. The body of the syringe may be formed from plastics or stainless steel or any other suitable material or combination of materials as appropriate.

The interconnection between the structure 11 and the syringe body need not be through screw threads. Especially in the case of a rigid stainless steel syringe body, the interconnection may be achieved in the manner of a push-in or snap-fit or other clip type connection.

Depending on the nature of the syringe and the mode of location of the cartridge therewithin, the structure 11 need not clip around or otherwise connect positively to or even engage the end of the cartridge. The cartridge may be held within the body of the syringe in conventional manner e.g. after side loading thereof through the usual side slot or aperture.

CLAIMS

1. A detachable housing for a syringe comprising a drug-containing cartridge (7) having a bung (8) at one end and a penetrable member (9) at the other end, the cartridge being adapted for connection to a needle (17) at the said other end, such that the needle (17) penetrates the penetrable member (9), and being adapted for connection to a plunger mechanism (1) at the said one end, so that the bung (8) can be moved down the cartridge (7) to expel the drug through the needle (17), characterised in that the cartridge (7) is provided with at least one separate structure (11) attachable relative thereto, said structure (11) being adapted for the said connection of the cartridge (7) to the needle (17) and providing means for releasable connection to the plunger mechanism (1), whereby the housing comprising the cartridge (7), the (or each) said structure (11), and the needle (17) can be detached from the plunger mechanism (1) for disposal together.

2. A housing according to claim 1 characterised in that there is one said structure (11) which is attachable to the said other end of the cartridge (7) and which is adapted for connection to the needle (17) and which provides the means for connection to the plunger mechanism (1).

3. A structure for attachment to a drug-containing cartridge of a syringe, which cartridge (7) has a bung (8) at a rearward end and a penetrable membrane (9) at a forward end, said structure (11) being adapted for attachment to a needle (17) and having means (16) for attachment relative to the forward end of the cartridge, and means (15) for attachment to a

plunger mechanism (1).

4. A structure according to claim 3 characterised in that the means (16) for attachment to the forward end of the cartridge comprises means arranged to fit around a neck at the forward end of the cartridge.

5. A structure according to claim 3 or 4 characterised in that said structure (11) is formed integrally with the needle (17).

6. A structure according to claim 3 or 4 characterised in that said structure (11) is formed separately from the needle and incorporates means (13) for connection thereto.

7. A structure according to any one of claims 3 to 6 characterised in that the means (15) for attachment to the plunger mechanism (1) comprises an outer peripheral retaining structure adapted to mate with a corresponding retaining structure at the end of a barrel extension (5) on the plunger mechanism (1).

8. A structure according to any one of claims 3 to 7 characterised by the provision of a sleeve (19) which is mounted on the structure (11) for longitudinal movement forwardly to sheath the needle (17) after use.

9. A structure according to any one of claims 3 to 8 characterised by the provision of a spring arrangement (22 or 24) on the structure (11) which acts to urge the cartridge in a direction away from the needle (17), a releasable retention device (23) being provided to bear on the top rim of the cartridge to resist said urging of the spring arrangement.

10. A housing according to claim 1 or 2 when using the structure of any

one of claims 3 to 9.

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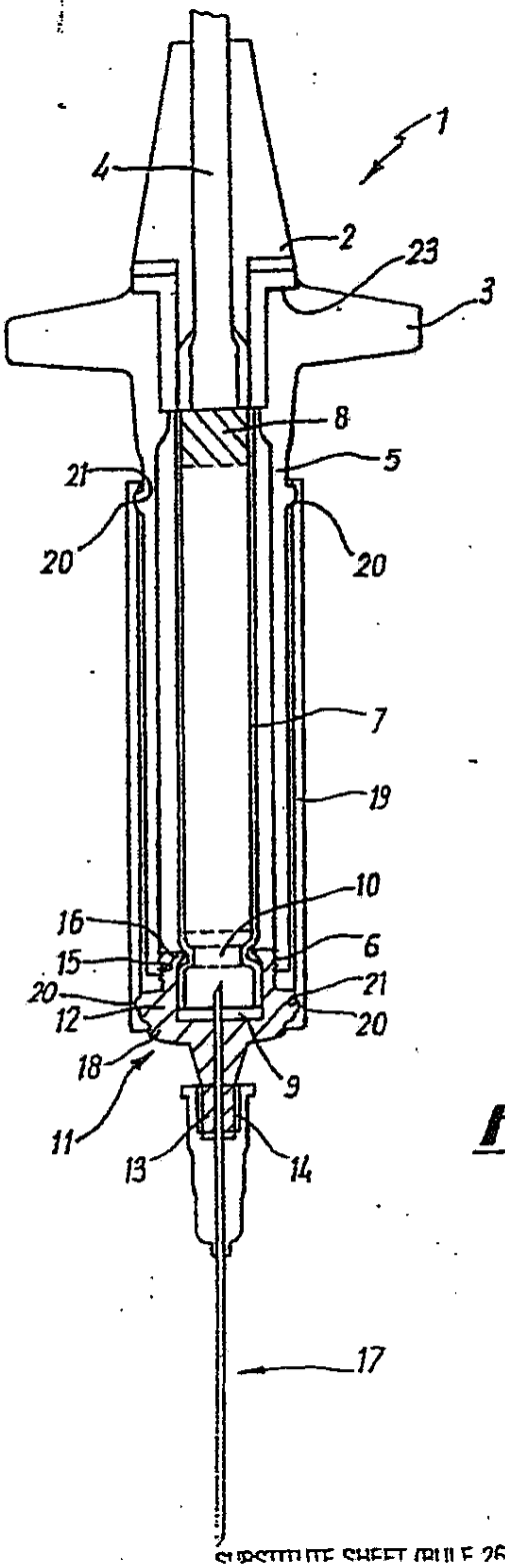

FIG.1

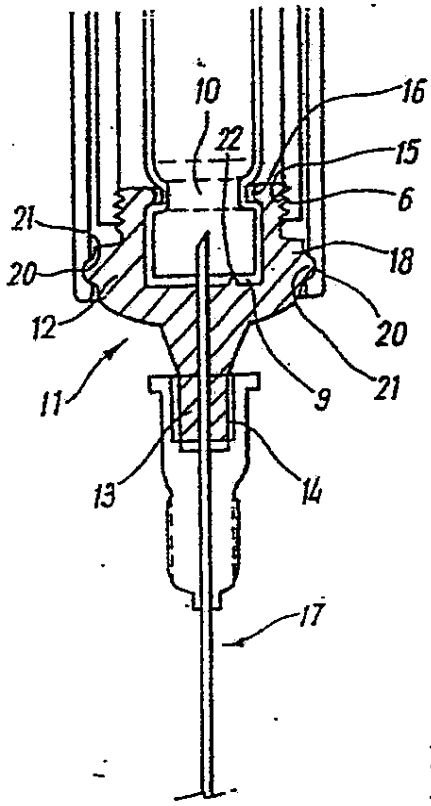
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FIG.2

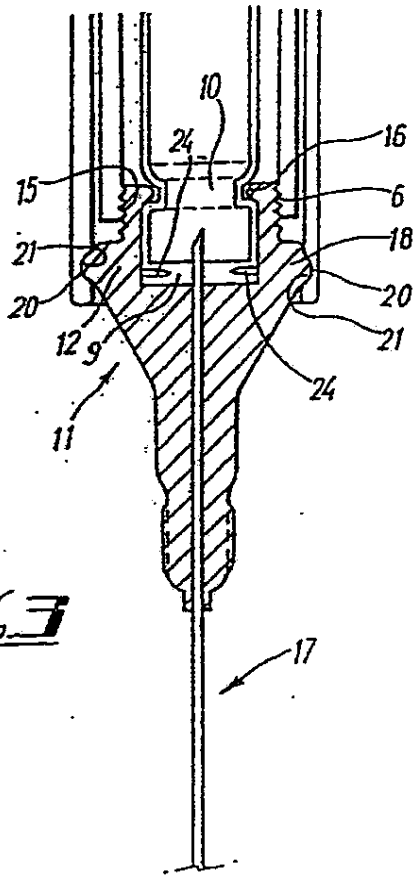
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FIG.3

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/GB 94/02475

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,2 778 359 (FRIEDMAN) 22 January 1957 see column 4, line 20 - line 36; figures	1-7,10 8
Y	WO,A,89 04680 (SELDOREN LTD) 1 June 1989 cited in the application see abstract; figures	8
X	US,A,3 825 002 (PAIGE) 23 July 1974 see column 3, line 58 - column 4, line 15; figures	1-7,10
X	US,A,2 671 450 (DANN) 9 March 1954 see the whole document	1-7,10
X	US,A,3 080 866 (FRIEDMAN) 12 March 1963 see column 3, line 57 - column 4, line 9; figures	1-7,10

☐ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 February 1995	09.03.95

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat Application No
PCT/GB 94/02475

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-2778359	22-01-57	NONE		
WO-A-8904680	01-06-89	DE-D-	3887531	10-03-94
		EP-A-	0394295	31-10-90
		GB-A-	2230193	17-10-90
US-A-3825002	23-07-74	NONE		
US-A-2671450	09-03-54	NONE		
US-A-3080866	12-03-63	NONE		

(12) PATENT ABSTRACT
(19) AU (11) AU-A -73 632/81

(54) DISPOSABLE VIAL-SYRINGE

(75) DASKAL, G.

(21) 73 632/81 (22) 3.8.81 (24) 3.8.81
(43) 10.2.83
(51)[3] A61M 5/18

(57) Claim 1. A disposable medicament injector containing its own vial and the vial being 'cylindrical' in shape and having a stopper at each end and the anterior end stopper being able to be pierced by a needle and the (rear) end stopper of the vial being also the anterior part of the plunger and the movements of this anterior part of plunger being inside the vial during use and the medicament - containing vial being enclosed inside the body of a disposable syringe so that these two structures are presented as one structure in a disposable vial / syringe.

Form 10

PATENTS ACT 1952

COMPLETE SPECIFICATION

(ORIGINAL)

FOR OFFICE USE

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Int. Cl:

Application Number:
Lodged:

Complete Specification—Lodged:
Accepted:
Lapsed:
Published:

Priority:

Related Art:

TO BE COMPLETED BY APPLICANT

Name of Applicant: GEORGE DASKAL

Address of Applicant: 57 JOHNSTON ST. ANNANDALE, SYDNEY 2038

Actual Inventor: GEORGE DASKAL

Address for Service: AS ABOVE

Complete Specification for the invention entitled: DISPOSABLE VIAL / SYRINGE

The following statement is a full description of this invention, including the best method of performing it known to me:—

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* Note: The description is to be typed in double spacing, pica type face, in an area not exceeding 250 mm in depth and 170 mm in

There exists at present in the field of Dental Analgesia several methods of giving injections. The two most common methods are:

(1) the use of a disposable pre-sterilised cartridge containing the anaesthetic drug and a re-usable metal syringe, and

(2) disposable standard plastic syringe and glass vial containing the anaesthetic drug. The vial is broken and the anaesthetic drug is aspirated into the syringe immediately prior to use in injection procedure.

This patent application presents a syringe which is disposable but which also contains its own drug. It can be said to be a vial / syringe combination. This disposable vial / syringe will also receive a needle which is the operator's choice (in needle length and needle bore size).

The disposable vial / syringe can be pre-sterilised and transported in a sterile state inside a suitable package. Hence, this disposable vial / syringe is ready for use as soon as its protective package is opened. There is no need for further sterilisation prior to use nor for any loading of cartridges or aspirating of anaesthetic drugs. (This eliminates these tedious procedures in a dental surgery and reduces time prior to injections as the disposable vial / syringe is ready for use as soon as its protective package is opened.)

This disposable vial / syringe has a further advantage in the dental surgery in that it has no visible metal parts and it is also smaller than the conventional metal syringe that receives disposable cartridges - both these features make it considerably less threatening to the patient. (Very important in dental surgery use.)

In the broader field of general medical use this disposable vial / syringe has the following advantages:

(1) Emergency use at site of accident because it is ready for immediate use and requires no further sterilisation.

(2) In Third World countries where sterilisation facilities are poor and it requires no further sterilisation prior to use.

(3) With the armed forces in combat situations or during training where equipment carried is kept to a minimum and ability to be used without further sterilisation is an advantage.

The invention is now described in detail with reference to accompanying drawings and numerals relating to parts on the drawings.

The disposable vial / syringe consists of a body of disposable vial / syringe and a plunger. The body is made up of parts labelled 1,2,3,4,5,6,7,11 and the plunger is made up of parts labelled 8,9,10.

Parts 1,2,3,7,8,10,11 are plastics.

Parts 6 and 9 are rubber.

Part 5 is metal.

Part 4 is glass.

The glass cylinder part 4 with the rubber parts 6 and 9 contain the drug to be injected.

Part 6 is immovable, but this rubber part is pierced by the needle (when the needle is attached to part 7) so that the drug can be injected. Part 6 is held on the glass cylinder by metal part 5.

Part 9 is movable by the application of a light force on plunger part 10 and this force must be applied in a line approximately along the long axis of part 4 and the movement of part 9 is also along the long

axis of part 4 (inside the cylinder formed by part 4). For movement of plunger 9 to occur the needle must have first pierced part 6.

Part 1 is the major plastic part of the body of the disposable vial / syringe and houses the drug - containing compartment (4,6,9).

Projections 3 and 2 are on either side of the first and second fingers when the syringe is held in the hand ready for use. Part 2 is in front of the fingers and part 3 is behind the fingers (front and back correspond to operator's front and back when the syringe is held inposition ready for use).

During injection procedure the fingers (first and second) press against part 3 while the thumb presses against part 10 and as the drug is expelled and the plunger moves inside the body of the disposable vial / syringe, the distance between 3 and 10 becomes smaller.

The projections labelled part 2 and the ring shape of 10 allow for aspiration (negative injection).

Aspiration is performed by pressing against 2 with back of first and second fingers and pressing against 10 with back of thumb so that the distance between 2 and 10 is lengthened.

Aspiration is important during block injections to ensure that the needle has not entered a blood vessel prior to injection of the drug. (If needle has entered a blood vessel then blood will be seen in the drug compartment during aspiration procedure.)

The plunger consists of parts 8,9 and 10. Part 10 is a ring into which the thumb of the operator fits.

Part 8 has an end that is conical shaped so that it fits into the cavity in rubber part 9. The

shape of this cavity is such that the conical part of the plunger part 8 can easily enter but can only be removed with difficulty.

Part 7 is for attachment of the needle. This part 7 may be either luer lock or luer grip. The needle used must be "double ended". One end of the needle (shorter end) pierces rubber part 6 and the other end is used to penetrate tissues during the injection procedure.

The claims defining the invention are as follows:

Claim 1. A disposable medicament injector containing its own vial and the vial being 'cylindrical' in shape and having a stopper at each end and the anterior end stopper being able to be pierced by a needle and the (rear) end stopper of the vial being also the anterior part of the plunger and the movements of this anterior part of plunger being inside the vial during use and the medicament - containing vial being enclosed inside the body of a disposable syringe so that these two structures are presented as one structure in a disposable vial / syringe.

Claim 2. The invention of claim 1 with the plunger containing a ring structure (for the thumb) at its distal end and the syringe body having lateral projections with two of these projections immediately at the rear end of body of syringe and another two lateral projections a little distance anteriorly so that operator's fingers that grip the syringe body are bounded by these projections during use.

Claim 3. Invention of claim 1, wherein the vial cylinder containing the medicament is glass and stoppers of vial are rubber (natural or synthetic).

Claim 4. Invention of claim 1 where the syringe part of disposable vial / syringe, as well as the plunger, are made of one of the plastics.

Claim 5. Invention of claim 1 where the anterior projection from body of syringe that is to receive the needle, is of either luer lock or luer grip type.

Claim 6. The invention of claim 1 but where the invention is presented as two parts, one being the body of disposable vial / stringe together with the anterior part of the plunger that forms the rear end stopper of vial compartment, and the other part being the remaining part of plunger, and these two parts are assembled prior to use by pushing plunger part into cavity of distal end stopper.

The claims defining the invention are as follows:

Dated this 30th day of July 1981 GEORGE DASKAL

NAME OF APPLICANT
(BLOCK LETTERS)

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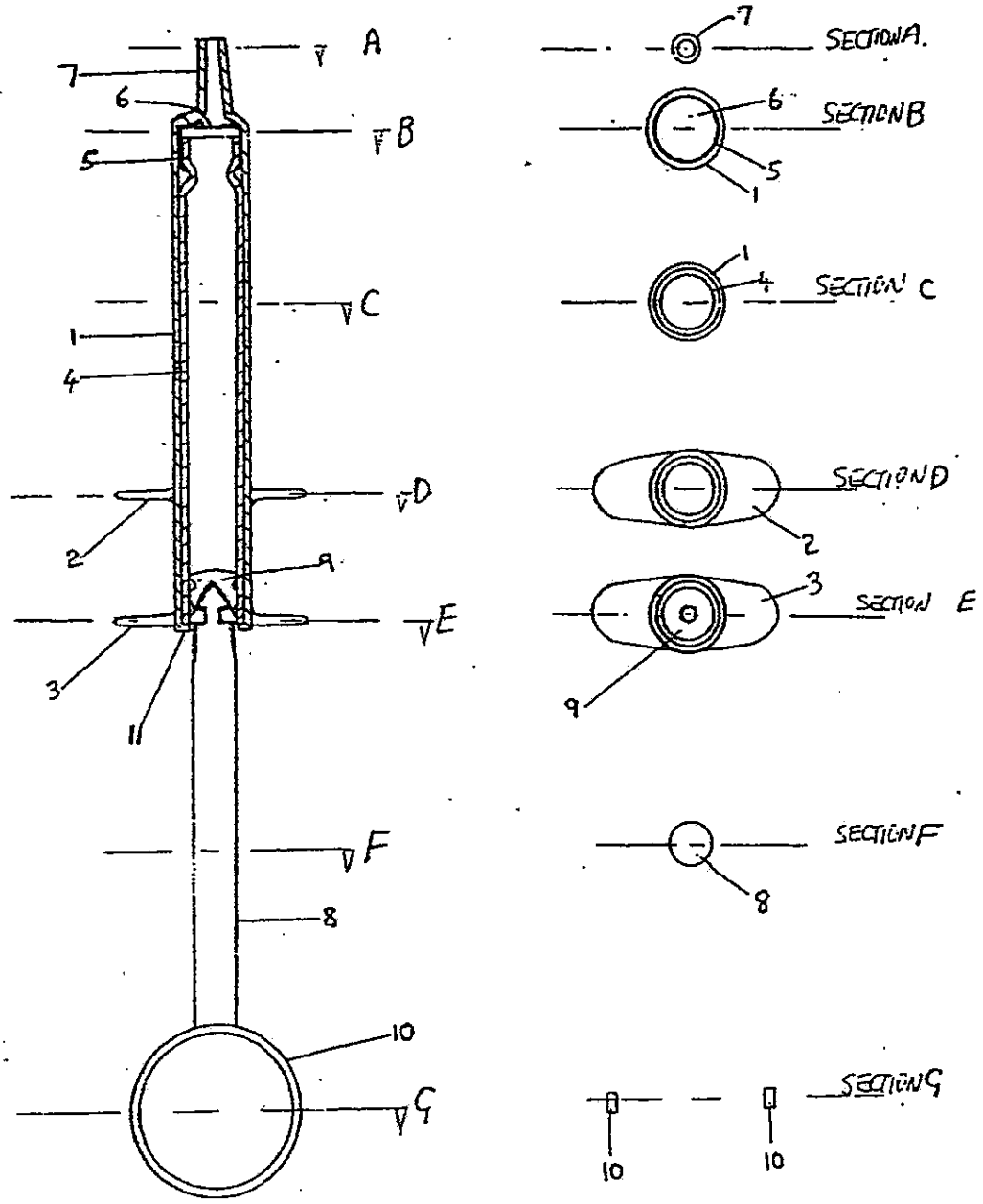
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SECTION B
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SECTION G

Gp 3734

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Group Art Unit: 3734

Filed: July 8, 1999

Examiner: To Be Assigned

For: Medical Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Transmittal of Supplemental Information Disclosure Statement
2. Supplemental Information Disclosure Statement
3. PTO-1449 Form
4. Copy of Reference

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on February 2, 2000.

Carol McFarlane
(name of person mailing paper)

Carol McFarlane
(signature of person mailing paper)

Attorney Docket No.:5533.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/349,748 Group Art Unit: 3734

Filed: July 8, 1999 Examiner: To Be Assigned

For: Medical Device

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

The supplemental information disclosure statement submitted herewith is being filed before the mailing date of a first Office action on the merits. Therefore, no fee is due.

Respectfully submitted,

Date: February 2, 2000

Elias J. Lambiris, Reg. No. 33,728
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Attorney Docket No.: 5533.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748 Group Art Unit: 3734

Filed: July 8, 1999 Examiner: To Be Assigned

For: Medical Device

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith a reference which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While this reference may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that said reference is "prior art" unless specifically designated as such.

The filing of this Supplemental Information Disclosure Statement shall not be construed as a representation that no other material references than this listed exists, or that a search has been conducted.

The reference is listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the reference is also enclosed.

The reference is as follows:

1. U.S. Patent 5,688,251.

It is respectfully requested that this reference be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of